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IN THE
SUPREME COURT OF THE UNITED STATES

FERRING B.V., PETITIONER,
–AND–
AVENTIS PHARMACEUTICALS, INC., PETITIONER,
v.
BARR LABORATORIES, INC., RESPONDENT.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Pursuant to this Court's holding in *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 816 (1945), a federal court may invoke its inherent equitable powers to render unenforceable an otherwise valid patent where the patentee has engaged in "inequitable conduct" during prosecution of the patent application before the United States Patent & Trademark Office ("PTO"). This Court characterized such "inequitable conduct" as a form of unclean hands. Lower courts have formulated a test for evaluating whether a patentee engaged in "inequitable conduct" during patent prosecution, allowing this doctrine to be invoked generally whenever (1) the patentee misrepresented or did not provide the PTO with "material" information and (2) the patentee did so with an "intent" to deceive. The questions presented in this case are:

1. Whether the United States Court of Appeals for the Federal Circuit has improperly expanded the scope of the inequitable conduct doctrine by lowering the threshold of what constitutes "material" information that a patentee must disclose to the PTO so as to include information that has no bearing on patentability.

2. Whether the United States Court of Appeals for the Federal Circuit has improperly expanded the scope of the inequitable conduct doctrine by lowering the threshold for establishing intent to deceive the PTO so as to include a judicial determination that the applicant "knew or should have known" the information not provided to the PTO was "highly material."

LIST OF PARTIES

The names of all parties in the court whose judgment is sought to be reviewed appear in the caption of this Petition for a Writ of Certiorari.

CORPORATE DISCLOSURE STATEMENT

Counsel for petitioners certifies as follows:

All parent corporations and publicly held companies that own 10 percent or more of petitioner Ferring B.V. are as follows: Ferring B.V. is a wholly-owned subsidiary of Ferring Holding S.A., Switzerland.

All parent corporations and publicly held companies that own 10 percent or more of petitioner Aventis Pharmaceuticals, Inc. are as follows: Aventis Pharmaceuticals, Inc. is a subsidiary of Aventis Holdings, Inc., which is a subsidiary of Aventis Inc., which is a subsidiary of sanofi-aventis, a public corporation organized under the laws of France. A minority interest in Aventis Pharmaceuticals, Inc. is held by Aventis Beteiligungsverwaltung GmbH, which is a subsidiary of a Aventis Pharma Holdings GmbH, which is a subsidiary of Hoechst A.G., which is a subsidiary of sanofi-aventis S.A.

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OPINIONS BELOW

The opinion of the United States Court of Appeals for the Federal Circuit is reported at 437 F.3d 1181 (Fed. Cir. 2006) and is set forth in the Appendix ("App.") at App. 1a-49a. The circuit's original and revised orders denying the Petition for Panel Rehearing and Rehearing *En Banc* (App. 86a-87a, 88a-89a) are unreported. The decision of the district court (App. 50a-85a) is unreported.

STATEMENT OF JURISDICTION

The United States Court of Appeals for the Federal Circuit entered its judgment in this case on February 15, 2006, denied the Petition for Panel Rehearing and Rehearing *En Banc* on April 10, 2006, and issued a revised order denying the Petition for Panel Rehearing and Rehearing *En Banc* on April 12, 2006. Chief Justice Roberts issued an order on June 15, 2006, extending the time to file the petition for a writ of certiorari to September 11, 2006. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTES AND REGULATIONS INVOLVED

In shaping the "inequitable conduct" doctrine at issue in this case, courts have looked at times to the regulations governing the patent procurement process to assess what information the United States Patent and Trademark Office ("PTO") considers important to that process. The duty to disclose material information to the PTO is governed by 37 C.F.R. § 1.56 ("Rule 56"). The 1990 version of Rule 56 in effect at the time of the prosecution of the patent-in-suit is reproduced in full at App. 90a-94a. In 1992, the PTO substantially revised this regulation, and these changes are reflected in the current regulation, reproduced in full at App. 95a-97a.

STATEMENT OF THE CASE

This case presents important questions regarding the contours of the "inequitable conduct" doctrine, pursuant to which courts may refuse all enforcement of otherwise valid patents. This Court promulgated the inequitable conduct doctrine more than sixty years ago in accordance with the unclean hands maxim in order to enforce "minimum ethical standards" in cases of extreme misconduct by persons prosecuting patent applications at the PTO.[1] *Precision Instrument Mfg. Co. v. Automotive Maint. Mach. Co.*, 324 U.S. 806, 816 (1945). Since then, the Federal Circuit has vastly expanded the doctrine's reach in a manner inconsistent with *Precision,* such that parties now invoke it routinely as a defense to patent infringement claims, and the resulting doctrine operates in considerable tension with the PTO's statutory authority to govern the conduct of proceedings before it, *see* 35 U.S.C. § 2(b)(2)(A).

According to the Federal Circuit, whether a patent applicant has engaged in inequitable conduct during patent prosecution turns on: (1) whether the applicant misrepresented or did not provide the PTO with "material" information and (2) whether the applicant did so with an "intent" to deceive the PTO. However, in applying these requirements, the Federal Circuit has strayed far from the inequitable conduct doctrine's equitable roots. The notion of "materiality" that the Federal Circuit now employs is sufficiently broad that courts may find materiality—as the Federal Circuit did here—without any proof that the PTO would have considered the information to be material to its administrative process. Moreover, in assessing whether the

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[1] The abbreviation PTO will be used in this brief to also refer to the "Patent Office," which was the agency's name prior to 1976.

applicant had the requisite intent, the Federal Circuit has applied a "sliding scale" that permits a factual finding of an intent to deceive the PTO based on no more than a negligence finding, *i.e.*, that the applicant "should have known" that information not provided to the PTO was material, if coupled with a judicial determination that the undisclosed information was "highly material."

The dramatic transformation of the inequitable conduct doctrine has produced circuit splits and conflicts with this Court's precedents, and has interfered with the PTO's ability to regulate practice before the agency. The practical ramifications of the expansion of the doctrine and the uncertainty surrounding its application (and misapplication) are far-reaching. The enforceability of otherwise valid patents is regularly challenged in litigation, frustrating the incentive goals of the patent system, adversely affecting decisions to invest in innovative technologies,[2] and escalating patent litigation costs. In fact, the National Academy of Sciences and the National Academy of Engineering ("National Academies of Science and Engineering"), through the National Research Council, have recommended abolishing the inequitable conduct doctrine "to reduce the cost and increase the predictability of patent infringement litigation outcomes, and to avoid other unintended consequences." *See* National Research Council, A Patent System for the 21st Century (2004), http://www.nap.edu/html/patentsystem/0309089107.pdf (last

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[2] Patents have become the backbone for capital investment decisions for small and large companies alike. Patents drive or greatly affect external investment decisions, venture capital investments, allocation of investment capital, and company stock appreciation. A rule of law that creates uncertainty in a property rights system thus constitutes risk for the investment community, and that greater risk leads to less investment.

accessed Sept. 8, 2006) [hereinafter "A Patent System"].

I. The Patent-in-Suit

This is a patent infringement action in which Ferring B.V. ("Ferring") and Aventis Pharmaceuticals, Inc. ("Aventis") seek to enforce U.S. Patent No. 5,047,398 (the "'398 patent"), entitled "DDAVP Antidiuretic and Method Therefor." C.A. App. 59-61. The '398 patent is directed to antidiuretic compositions containing 1-deamino-8-D-arginine vasopressin (also known as DDAVP) and methods of administering such compositions for treating diabetes insipidus. Ferring is the owner of the '398 patent, and Aventis is the exclusive licensee and sells DDAVP® in the United States.

The invention described in the '398 patent relates to a new, safe, and simple method of administering DDAVP, *i.e.*, via tablets which are swallowed and absorbed in the gastrointestinal tract. C.A. App. 60. This was an important advance over the prior art, because, prior to the invention, it was generally believed that proteins and peptides, such as DDAVP, decomposed in the stomach and intestines without substantial, or any, absorption. *Id.* Consequently, before the invention, DDAVP was administered inefficiently and inconveniently via sprays or plastic tubes for absorption through the nasal passages.

II. The Proceedings Before the PTO and the Basis of the Inequitable Conduct Findings

The Federal Circuit's inequitable conduct holding is based on the trial court's determination that certain declarations filed with the PTO did not contain information regarding the declarants' prior relationships with Ferring.

The claims in the patent application that issued as the

'398 patent were initially rejected by the PTO as anticipated by and obvious in light of the "Zaoral patent" (U.S. Patent No. 3,497,491). The PTO interpreted Zaoral's use of "peroral" to cover administration of DDAVP in a pill form suitable for absorption in the gastrointestinal tract ("GI"). The applicants subsequently filed a continuation application in December 1985, and, in an interview with the PTO in May 1986, inventor Dr. Vilhardt explained that Zaoral used the term "peroral" to refer to buccal (inside the cheek) or sublingual (under the tongue) administration, not administration (absorption) via the GI tract. C.A. App. 4385. In response, the PTO "suggested that applicants obtain evidence from a non-inventor to the same effect." C.A. App. 2177. The PTO's official record of the interview, however, did not mention that "non-inventor" declarations were required. *See* C.A. App. 4385.[3]

In June 1986, the applicants filed a Preliminary Amendment accompanied by two declarations from Dr. Vilhardt (C.A. App. 3523-28, 3588-99) and declarations from two non-inventors, Drs. Myron Miller (C.A. App. 3634-58) and Paul Czernichow (C.A. App. 3601-32). The declarations explained that the term "peroral" was used in the Zaoral patent to refer to sublingual or buccal absorption, not absorption through the GI tract. Despite this declaration evidence, the PTO maintained its rejection. In response, the applicants appealed to the PTO Board of Patent Appeals and Interferences ("the Board"), which disagreed with the PTO Examiner and reversed the rejection. The Board entered a different obviousness rejection based on the Zaoral patent in

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[3] In accordance with PTO practice, "[a] complete written statement as to the substance of *any* face-to-face or telephone interview with regard to an application *must be made of record in the application*, whether or not an agreement with the examiner was reached at the interview." MPEP § 713.04 (emphasis in original) at C.A. App. 4386.

combination with an article published by Vavra, and returned prosecution to the PTO Examiner.

In November 1990, applicants responded to the Board's rejection by filing an Amendment and a new declaration from Dr. Vilhardt and four additional non-inventor declarations from Drs. Miller and Czernichow (both of whom had submitted declarations in 1986 (C.A. App. 3634-58, 3601-32)), and two new declarants, Drs. Tomislav Barth (C.A. App. 3701-02) and I.C.A.F. Robinson (C.A. App. 3703-05). All were very accomplished scientists. The declarants explained that the Vavra article did not teach or suggest the absorption of DDAVP in the GI tract in humans. The PTO issued the '398 patent on September 10, 1991.

The declarations did not reflect the limited, prior relationships between three of the four non-inventor declarants[4] and Ferring. Dr. Czernichow, a Professor at the Hospital des Enfants-Malades in Paris, had participated in a small Ferring-funded DDAVP clinical trial for which he was not compensated by Ferring. Dr. Barth, a Professor at the Academy of Science of the Czech Republic at the time of his declaration, had worked on several projects for Ferring while at the Czech Academy. Dr. Robinson, the Head of the Division of Molecular Neuroendocrinology at the National Institute for Medical Research in London at the time of his declaration in 1990, had been a Ferring research director in 1985-86 and was a paid Ferring consultant for some months before that and again from 1986-89.

There was no factual finding or evidence of record that

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[4] Dr. Miller, Chief of Geriatric Medicine at the Veterans Administration Medical Center in Syracuse, the remaining non-inventor declarant who submitted declarations in 1986 and 1990, had no relationship with Ferring at any time.

Drs. Czernichow, Barth, Miller, or Robinson had relationships with Ferring at the time of their declarations, had financial interests in the patent application that led to the '398 patent, or were compensated in any way for their declarations. The record is also devoid of any evidence that the substance of their declarations, *i.e.*, the scientific statements they made to the PTO, was inaccurate or untruthful. Nor is there any evidence that the PTO would have considered such past relationships with Ferring relevant to the patentability issues before the PTO and the declaration discussions regarding the art cited by the PTO. Indeed, although the PTO suggested during an interview that the applicants could submit "non-inventor" declarations with respect to the Zaoral patent, the PTO did not so require in the official Interview Summary Form (C.A. App. 4385), let alone ask for declarations from parties having no prior connections with Ferring.

There was also no evidence that information regarding the prior connections Drs. Czernichow, Robinson, and Barth had with Ferring was intentionally withheld from the PTO. In fact, there was no evidence that Dr. Vilhardt, himself a distinguished scientist and professor at the University of Copenhagen, even knew of the prior connections between Dr. Czernichow and Ferring.[5]

III. The Infringement Suit and the Decision of the Trial Court

In December 2002, Ferring and Aventis filed suit in the

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[5] From 1977 to 1980, Dr. Vilhardt worked at Ferring as Research and Medical Director. In 1980, he returned to the University of Copenhagen but remained a scientific consultant for Ferring from 1980 until about 1987. Ferring continued to provide funding for Dr. Vilhardt's research until 1990.

United States District Court for the Southern District of New York, asserting that Barr Laboratories, Inc. ("Barr") infringed the '398 patent by filing its abbreviated new drug application seeking FDA approval to market a generic version of the patented DDAVP tablets prior to the expiration of the '398 patent. In February 2005, the district court (Brieant, J.) granted Barr's motions for summary judgment on its inequitable conduct defense and on its non-infringement counterclaim. App. 85a. Specifically, the court held the '398 patent unenforceable for inequitable conduct on the grounds that inventor Dr. Vilhardt had not informed the PTO of prior connections between Ferring and declarants Drs. Robinson, Barth, and Czernichow.

As to materiality, the district court nominally applied the PTO's pre-1992 materiality standard, *i.e.*, "information is material where there is a substantial likelihood that a reasonable examiner would consider it important," holding that declarations submitted in support of a pending patent application are generally considered material and by extension that the prior connections with Ferring were "highly material," without any finding that the substance of any of the declarations was incorrect. App. 61a, 68a. The district court concluded that, even if the declarants were "perfectly capable of objectivity," the PTO should have been informed of "the connections and prior relationships between these experts and Ferring." App. 66a. The district court then found an "intent to deceive" the PTO because "it must have been clear to Dr. Vilhardt at the preliminary meeting with the examiner that a non-inventor affidavit was sought for purposes of obtaining objective evidence that the invention was not anticipated by the prior art or obvious." App. 67a. Based on the foregoing, the court held on summary judgment that inequitable conduct had occurred as a matter of law.

IV. The Decision of the Federal Circuit

The Federal Circuit panel majority affirmed the district court's grant of summary judgment on the defense of inequitable conduct and did not reach the trial court's rulings on patent infringement. App. 2a. The Federal Circuit also cited the pre-1992 PTO regulation, but then stated that "[a]ffidavits are inherently material, even if only cumulative," and that "it is especially important that the examiner has all the information needed to determine whether and to what extent he should rely on declarations presented by the applicant." App. 14a n.9, 11a. The Federal Circuit then invoked "[t]he general law of evidence," which "has long recognized that the testimony of any witness may be rendered suspect by a past relationship with a party," App. 11a, explaining that "[a] witness's interest is always pertinent to his credibility and to the weight to be given to his testimony, and relevant interests are not limited to direct financial interests," App. 13a. The Federal Circuit thus was willing to invoke the inequitable conduct doctrine—which this Court has sparingly used as punishment for unclean hands—due to nothing but a potential for bias.

As to intent, the majority held that an intent to deceive can be inferred from evidence of negligence. Specifically, the Federal Circuit stated

> that summary judgment is appropriate on the issue of intent if there has been a failure to supply highly material information and if the summary judgment record establishes that (1) the applicant knew of the information; (2) the applicant *knew or should have known* of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding.

App. 19a (emphasis added). In finding under this standard that Dr. Vilhardt intended to mislead the PTO, the Federal Circuit stated that: (1) Barr had "established that Vilhardt knew of significant past relationships of at least two declarants," (*i.e.*, 1990 declarants Robinson and Barth); (2) Dr. Vilhardt was "on notice that disinterested affidavits were necessary, and knew or should have known that the Ferring affiliations were material"; and (3) Dr. Vilhardt had not submitted an affidavit as to his own good faith in Ferring's Opposition to Barr's summary judgment motion on the issue. App. 19a-22a.

Judge Newman vigorously dissented. In a 21-page dissent, Judge Newman criticized the majority opinion for departing from the standard established in the Federal Circuit's *en banc* decision in *Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867 (Fed. Cir. 1988), which held that "a finding that particular conduct amounts to 'gross negligence' does not of itself justify an inference of intent to deceive." App. 29a-32a. In Judge Newman's words, the majority opinion served to

> impose a positive inference of wrongdoing, replacing the need for evidence with a "should have known" standard of materiality, from which deceptive intent is inferred, even in the total absence of evidence. Thus the panel majority infers material misrepresentation, infers malevolent intent, presumes inequitable conduct, and wipes out a valuable property right, all on summary judgment, on the theory that the inventor "should have known" that something might be deemed material.

App. 32a. The dissent described the inference that the scientific opinions of the "distinguished" declarants were

"submitted with deceptive intent as a travesty." App. 35a.

Judge Newman further stated that the "past affiliations" of the declarants were "not clearly and convincingly material as a matter of law." App. 33a. Judge Newman also noted that the majority's finding of materiality "is not substantive scientific materiality, but materiality *per se* of the relationship of the affiant to the applicant." App. 36a. "Whether a past relationship between a declarant and the patent applicant is material to patentability depends on the facts of the relationship and the nature of the declaration. It is not *per se* material; and failure to explain the relationship is not *per se* deception." App. 39a. Finally, Judge Newman stated that the majority had defied the rules of summary judgment by drawing "adverse inferences against the party opposing summary judgment" in lieu of the requisite "clear and convincing evidence of materiality and deceptive intent." App. 47a.

REASONS FOR GRANTING THE PETITION

This case involves the Federal Circuit's exercise of its inherent judicial powers to refuse enforcement of otherwise valid patents where there is real misconduct before the PTO, the administrative agency tasked with examining and issuing patents. In the entire history of the United States patent system, this Court has sustained such a use of inherent judicial power in the patent context precisely once, in *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945), where the inventor had engaged in perjury and the inventor's assignee had entered into contracts to continue to hide perjury from the PTO and the courts. This Court held that the inherent equitable powers of federal courts could be invoked under the unclean hands doctrine to refuse all enforcement of the "perjury tainted patents and contracts" because the patentee's inequitable conduct did not "conform to minimum ethical

standards." *Id.* at 816.

Since *Precision*, the Federal Circuit has adopted a test for inequitable conduct that focuses on: (1) whether the applicant misrepresented or did not provide the PTO with "material" information and (2) whether the applicant did so with an "intent" to deceive the PTO. Although these requirements are consistent with this Court's reasoning in *Precision*, the lower courts, in applying the requirements, have strayed far beyond the narrow power recognized in *Precision* and developed a body of inequitable conduct law through capacious interpretation of the standards for establishing "materiality" and "intent."

This case is a telling example. Here, on summary judgment, the Federal Circuit held the '398 patent unenforceable and destroyed a significant property right because the patentee did not inform the PTO of prior contacts and limited relationships that some of the declarants had with Ferring. This omission pales in comparison to the intentional misconduct that occurred in *Precision*. Indeed, the Federal Circuit found inequitable conduct without pointing to any evidence or PTO regulation indicating that the PTO considers such prior relationships material to its patentability determination. Moreover, in finding an intent to deceive the PTO, the Federal Circuit used a negligence standard, concluding that the applicant "should have known" of the materiality of the undisclosed information.[6]

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[6] In testimony before the United States Senate Committee on the Judiciary, Philip S. Johnson, Esq., Chief Patent Counsel of Johnson & Johnson, testified that in the *Ferring* case the Federal Circuit "affirmed summary judgment of inequitable conduct under what appears to be a new duty of candor, applying a might-have-been-asked-should-have-been-answered standard, for deciding what must have been told to a patent examiner." Hearing on Perspectives on Patents: Post-Grant

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Because the inequitable conduct doctrine has been enlarged far beyond the narrow bounds of its unclean hands origins in *Precision*, it has become, as the Federal Circuit once observed, "an absolute plague" upon the patent system with "charg[es of] inequitable conduct in almost every major patent case." *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988). The vast modern expansion of the doctrine—based neither on congressional action nor PTO regulation, nor on any decisions of this Court—has given rise to (i) circuit splits between the Federal Circuit and the regional circuits (as well as intracircuit splits); (ii) conflicts between the Federal Circuit and the PTO; (iii) an inconsistency with the fundamental teachings of this Court concerning the scope and use of the inherent equitable powers of federal courts; (iv) inconsistency between the approach taken for policing misconduct before the PTO and the approach taken for addressing misconduct before other federal administrative agencies; and (v) a call for abolition or dramatic reform of the doctrine from the nation's leading scientific institutes, the National Academies of Science and Engineering.

I. Traditionally Courts Have Refused to Enforce Patents Because Of Administrative Wrongdoing Only in Exceptionally Rare Circumstances

For more than one hundred years, a private party could not assert, even as a defense to an infringement action, "that the patentee had secured his grant by fraud or corruption."

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Review Procedures and Other Litigation Reforms Before the S. Comm. on the Judiciary, Statement of Philip S. Johnson, Chief Patent Counsel, Johnson & Johnson, May 23, 2006, http://judiciary.senate.gov/testimony.cfm?id=1911&wit_id=5367 (last visited Sept. 8, 2006).

2 WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 717, at 458 (1890). In the mid-1940s, however, this Court recognized a narrow exception to this traditional rule in cases where a party asserting patent rights has been involved in blatant fraud and obstruction of justice. The first suggestion of an exception came in dicta in *Hazel-Atlas Glass Co. v. Hartford Empire Co.*, 322 U.S. 238 (1944). In *Hazel*, the patentee paid handsomely for the fabrication of spurious evidence that it relied upon both during PTO prosecution and in subsequent patent infringement litigation. Years later, the infringement defendant learned the truth about the fraudulent activities and petitioned the courts for relief from the old judgment of infringement. The Supreme Court held that such relief was permissible because the fraud "demands the exercise of the historic power of equity to set aside fraudulently begotten judgments." *Id.* at 245. The Court stressed that the case presented "a deliberately planned and carefully executed scheme to defraud not only the [PTO] but the Court of Appeals," *id.* at 246, and that the facts were appropriate for the "judicially devised remedy" permitting "[e]quitable relief against fraudulent judgments," *id.* at 248. The Court ruled that the "total effect of all this fraud, practiced both on the [PTO] and the courts, calls for nothing less than a complete denial of relief to [the patentee]," and stated in dicta that, "[h]ad the District Court learned of the fraud on the [PTO] at the original infringement trial, it would have been warranted in dismissing [the patentee's] case." *Id.* at 250.

The year after *Hazel*, this Court decided *Precision*. The inventor, Larson, was working for Precision when he applied for a patent on an improved "tail piece" for a particular kind of wrench. *Automotive Maint. Mach. Co. v. Precision Instrument Mfg. Co.*, 143 F.2d 332, 334 (7th Cir. 1944). During the course of patent prosecution, Larson fraudulently expanded his claims to encompass the entire wrench. To

support the broader claims, Larson filed a false affidavit concerning his purported invention of the wrench. The PTO declared an interference between Lawson's application and an application being prosecuted by Automotive, which also claimed to have invented the wrench. During the interference, Automotive obtained proof that Larson's affidavit was fraudulent. *Precision*, 324 U.S. at 809-10.

If Automotive had disclosed the fraud to the PTO, it could have prevailed in the interference and obtained patent rights to the wrench. However, Automotive would then have had no rights to patent claims covering Larson's innovative tail piece. Rather than disclose the fraud to the PTO, Automotive used its knowledge of Larson's perjury to achieve a settlement of the interference whereby Automotive received (1) Larson's concession of the whole interference; (2) an assignment of the remaining claims in Larson's perjury-tainted patent application; and (3) a commitment from Larson and his firm, Precision, never to question the validity of the subsequently issued patents. Thereafter, patents issued to Automotive from both its own application and the perjury-tainted application originally filed by Larson.

Later, Precision began manufacturing wrenches and Automotive sued Precision for infringement and breach of contract. This Court held that Automotive's lawsuit should be dismissed because a federal court should not assist in the enforcement of "perjury-tainted patents and contracts." *Id.* at 816. The Court stressed that Automotive's misconduct lay in exploiting rather than reporting Larson's perjury and that the conduct did not "conform to minimum ethical standards." *Id.* Requiring disclosure of such known fraud to the PTO when it is uncovered reinforces the agency's responsibility to "pass upon the sufficiency of the evidence" and "to safeguard the public in the first instance against fraudulent patent monopolies." *Id.* at 818. Automotive's exploitation of fraud also extended to the courts, and "inequitable

conduct impregnated Automotive's *entire cause of action*," not merely the administrative proceeding, and such inequitable conduct "justified dismissal by resort to the unclean hands doctrine." *Id.* at 819 (emphasis added).

For at least the next twenty years, *Precision* was interpreted narrowly by lower courts and applied, if at all, only in extreme cases where patent applicants made clear, intentional misrepresentations which bore directly on the issue of patentability.[7]

II. The Lower Courts Expanded the Inequitable Conduct Doctrine by Rejecting Then-Current Administrative Practice

More than two decades after this Court's decision in *Precision*, the doctrine of inequitable conduct underwent a dramatic expansion in some appellate courts. Pivotal in triggering the surge in inequitable conduct litigation was *Norton v. Curtiss*, 433 F.2d 779 (C.C.P.A. 1970), a decision by the Court of Customs and Patent Appeals ("CCPA"), a predecessor of the Federal Circuit that had jurisdiction to review decisions of the PTO. In an interference proceeding, the PTO had rejected one applicant's argument that the PTO should strike a competing application for fraud on the PTO. Although the CCPA ultimately sustained the agency's action, it elaborated on the law concerning fraud on the PTO and held that the agency was applying the materiality and intent elements too narrowly.

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[7] *See, e.g., Armour & Co. v. Wilson & Co.*, 274 F.2d 143, 148 (7th Cir. 1960); *Haloro, Inc. v. Owens-Corning Fibreglas Corp.*, 266 F.2d 918, 919 (D.C. Cir. 1959); *Mas v. Coca-Cola Co.*, 163 F.2d 505, 507 (4th Cir. 1947). We have not identified any case during this twenty year period where a court of appeals affirmed the use of the inequitable conduct doctrine to refuse enforcement of issued patents.

Norton recognized that, in the past, "'materiality' ha[d] generally been interpreted to mean that if the [PTO] had been aware of the complete or true facts, the challenged claims would not have been allowed." *Id.* at 794. The CCPA, however, urged a broader test that included the subjective considerations of the examiner and the applicant. Regarding intent, the CCPA held that the PTO had applied the wrong standard, "narrow[ing] the requirement almost to that of proving actual intent." *Id.* at 796. In the CCPA's view, "it may suffice to show nothing more than that the misrepresentations were made in an atmosphere of gross negligence as to their truth." *Id.*

III. The Expansion of the Inequitable Conduct Doctrine Has Generated Acknowledged Circuit Splits and Conflicts with Administrative Practice

A. Conflicting Standards of Materiality

In the dozen years between the decision in *Norton* and the creation of the Federal Circuit, a deep and widely recognized circuit split had developed. The Federal Circuit noted that "courts have utilized at least three distinct orders of materiality: (1) an objective 'but for' standard; (2) a subjective 'but for' standard; and (3) a 'but it may have been' standard." *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362 (Fed. Cir. 1984). The objective "but for" standard is the narrowest in its reach, as it requires a party asserting fraud to prove that but for the misrepresentation, the PTO would not have granted the patent. Although the first "but for" test had a substantial following prior to the CCPA's influential decision in *Norton*,[8] the circuit split that has developed since 1970 has

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[8] *See, e.g., Feed Serv. Corp. v. Kent Feeds, Inc.*, 528 F.2d 756, 762 (7th Cir. 1976); *Cataphote Corp. v. DeSoto Chem. Coatings, Inc.*,

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been dominated by the second and third tests, plus a new test created and applied by the Federal Circuit.

At least three circuits have applied the second test—the subjective "but for" test—which requires that a court determine whether the misrepresentation was a crucial factor or substantial cause of the granting of the patent. *See Skil Corp. v. Lucerne Prods., Inc.*, 684 F.2d 346, 350 (6th Cir. 1982); *Pfizer, Inc. v. Int'l Rectifier Corp.*, 685 F.2d 357, 359 (9th Cir. 1982); *Plastic Container Corp. v. Cont'l Plastics*, 607 F.2d 885, 900 (10th Cir. 1979). Other circuits have embraced the third test under which omissions or misrepresentations may be viewed as material if they *may* or *might* have resulted in a rejection of the patent application. *See CMI Corp. v. Barber-Greene Co.*, 683 F.2d 1061, 1066 (7th Cir. 1982); *Timely Prods. Corp. v. Arron*, 523 F.2d 288, 297-98 (2d Cir. 1975); *Monsanto Co. v. Rohm & Haas Co.*, 456 F.2d 592, 600 (3d Cir. 1972); *Trio Process Corp. v. L. Goldstein's Sons, Inc.*, 461 F.2d 66, 73 (3d Cir. 1972).

In *American Hoist*, the Federal Circuit explicitly acknowledged the use of the three materiality tests but adopted a fourth broader test under which information is deemed material where there is "a substantial likelihood" that a reasonable examiner would consider it "important" in deciding whether to allow the application to issue as a patent. *American Hoist*, 725 F.2d at 1362.

The pre-1992 Rule 56 articulated the same standard for materiality, *i.e.*, what "a reasonable examiner would consider . . . important." 37 C.F.R. § 1.56(a) (1991). In 1992, the

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450 F.2d 769, 773 (9th Cir. 1971); *Wen Prods. Inc. v. Portable Elec. Tools, Inc.*, 367 F.2d 764, 767 (7th Cir. 1966).

rule was "amended to present a clearer and more objective definition of what information the [PTO] considers material to patentability," PTO, Notice of Final Rulemaking, Duty of Disclosure, 57 Fed. Reg. 2021, 2024 (Jan. 17, 1992). The new rule articulates a fifth materiality standard, wherein information is material to patentability when it is not "cumulative" to information of record and it helps to establish "a *prima facie* case of unpatentability of a claim," or is "inconsistent" with the applicant's position on patentability. 37 C.F.R. § 1.56(b) (2006). Taken together, the pre-1992 and post-1992 versions of Rule 56 demonstrate that the PTO considers information material if it is new information that directly bears on the substantive question of patentability.

Nonetheless, the Federal Circuit has held that the new rule does not "supplant" the common law tests developed to enforce the "judicially created" inequitable conduct doctrine. *Digital Control, Inc. v. Charles Machine Works*, 437 F.3d 1309, 1315-16 (Fed. Cir. 2006). In effect, the Federal Circuit has ignored the PTO's view of materiality. *See* R. CARL MOY, MOY'S WALKER ON PATENTS § 2.9 at 2-23 n.2 (2005) (stating that the 1992 rule "has proven ineffective" in "overturn[ing] common-law precedents of the Federal Circuit").

That there is no specific PTO regulation or guideline requiring disclosure of all prior connections between declarants and applicants is yet another indication that these connections are not considered important by the PTO. As the Federal Circuit noted, "examiners have broad authority to request information that they deem relevant to the issue of patentability." App. 11a. Yet, the PTO here did not require disinterested declarations; did not inquire about any connections between the declarants and Ferring; did not request the CVs of Drs. Barth and Robinson whose declarations were submitted without them; and did not ask

whether the declarants were paid for their declarations (they were not).

B. Conflicting Standards of Intent

Prior to the creation of the Federal Circuit, there existed a three-way regional circuit split on the showing of "intent" necessary to trigger an inequitable conduct holding. Some circuits required scienter (*i.e.*, the patentee had knowingly and intentionally lied), while other circuits held that only a showing of gross negligence is sufficient. *Compare*, *e.g.*, *Scott Paper Co. v. Fort Howard Paper Co.*, 432 F.2d 1198, 1204 (7th Cir. 1970) ("Unclean hands can be asserted only if there has been a deliberate misrepresentation in the [PTO]."), *with Delong Corp. v. Raymond Int'l, Inc.*, 622 F.2d 1135, 1146 (3d Cir. 1980) (stating inequitable conduct requires at least a finding of "gross negligence"). One circuit (the First) adopted an intermediate position that embraced a sliding scale permitting a lower showing of intent if coupled with a greater showing of materiality, and vice-versa. *See Digital Equip. Corp. v. Diamond*, 653 F.2d 701, 716 (1st Cir. 1981).

Following its formation in 1982, the Federal Circuit initially required evidence of intentional misconduct. *See Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1383 (Fed. Cir. 1983). The Federal Circuit relaxed the intent standard shortly thereafter, however, holding that evidence of gross negligence could support an inequitable conduct finding. *See Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed. Cir. 1984).

The Federal Circuit again reversed course in its *en banc* decision in *Kingsdown*, expressly overruling *Driscoll* and holding that inequitable conduct required proof of an "intent to deceive" the PTO, and that "a finding that particular conduct amounts to 'gross negligence' does not of itself justify an inference of intent to deceive." *Kingsdown*, 863

F.2d at 876. *Kingsdown* did not, however, explicitly disavow or discuss the First Circuit's "sliding scale" theory and its application to the intent standard. That theory had been embraced by the Federal Circuit prior to *Kingsdown*. *See American Hoist*, 725 F.2d at 1363.

Recent cases, including this one, show that the Federal Circuit has now engrafted the sliding scale approach onto *Kingsdown*.[9] As the Federal Circuit panel majority held in this case, an "intent to deceive" sufficient to satisfy *Kingsdown* may be predicated upon a combination of a "high degree" of materiality coupled with a finding that the patentee "should have known" about the materiality of the omissions. Moreover, the procedural posture of this case—a finding of inequitable conduct on summary judgment—confirms that the Federal Circuit doctrine is not merely articulating that certain *permissible* inferences may be drawn from certain facts. Rather, intent to deceive is now being demonstrated *as a matter of law* in cases where the court determines that a "high degree of materiality" is coupled with negligence. But negligence is not intent.

The Federal Circuit's "should have known" standard is also inconsistent with current PTO regulations. During prosecution, a patent applicant has a legal and ethical "duty to disclose to the [PTO] all information *known* to that individual to be material to patentability as defined in this

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[9] *See, e.g., Abbott Labs. v. Torpharm, Inc.*, 300 F.3d 1367, 1380 (Fed. Cir. 2002) ("[T]he intent necessary to establish inequitable conduct is based on a sliding scale related to materiality of the omission."); *see also Novo Nordisk Pharms., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1359 (Fed. Cir. 2005); *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1239 (Fed. Cir. 2003); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed. Cir. 1997).

section." 37 C.F.R. § 1.56 (2006) (emphasis added). According to the PTO, the Rule was clarified in 1992 "to indicate that the duty of an individual to disclose information is based on the knowledge of that individual that the information is material to patentability." Duty of Disclosure, 57 Fed. Reg. 2021, 2022 (Jan. 17, 1992). This difference between the Federal Circuit standard and the PTO standard can only create needless confusion. The expanded judicial tests for intent and materiality force patent applicants to expend resources seeking and disclosing information that the PTO regulations and guidelines do not require and, in turn, the PTO must expend more resources reviewing this additional information.

Though the circuit splits on materiality and intent arose before the establishment of the Federal Circuit, this Court has made clear that such splits on patent issues remain significant in making certiorari decisions. *See Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 60 (1998); *see also Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 839 (2002).

IV. The Federal Circuit's Standards of Materiality and Intent Have No Foundation in This Court's Patent Decisions or in Other Areas of Law

A. The Federal Circuit's Materiality Standard

Neither in patent inequitable conduct cases nor in other substantive legal areas has this Court ever applied a materiality standard that could be triggered by the nondisclosure of information related to tangential matters. In *Precision*, for example, the patent applicant had filed a statement with the PTO providing false dates as to the conception, disclosure, drawing, description, and reduction to practice of his claimed invention, 324 U.S. at 809, and also falsely claimed that he was the sole inventor of the

entire wrench, *id.* at 810. These statements directly related to the patentability issue.

On the other hand, this Court has held that even an outright misrepresentation is not material where the misrepresentation raises a peripheral issue which does not impact the patentability of the claimed invention. In *Corona Cord Tire Co. v. Dovan Chemical Corp.*, 276 U.S. 358, 373-74 (1928), the inventor submitted blatantly false affidavits to the PTO claiming to have used his new vulcanization process to produce retail products when, in fact, the inventor had produced only some test sheets. This Court held that the misrepresentations, "though perhaps reckless, were not the basis for [the patent] or essentially material to its issue," and thus did not destroy the "reasonable presumption of validity furnished by the grant of the patent." *Id.* at 374.[10]

The standard of materiality applied by the Federal Circuit here also conflicts with the standard for materiality applied by this Court in statutory cases concerning fraud or misrepresentation. In *Kungys v. United States*, 485 U.S. 759, 770 (1988), the Court endorsed a standard under which "a concealment or misrepresentation is material if it 'has a natural tendency to influence, or was capable of influencing, the decision of' the decisionmaking body to which it was addressed." Three Justices (Justice Stevens joined by Justices Marshall and Blackmun) applied an even narrower standard of materiality; in their view, a misrepresentation

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[10] The *Corona* standard has been used by the lower courts in developing a "but for" standard of materiality for establishing fraud on the PTO, *i.e.*, a misrepresentation or omission is material only if "but for" the misrepresentation or omission, the patent would not have issued. *See, e.g., Corning Glass Works v. Anchor Hocking Glass Corp.*, 253 F. Supp. 461, 469 (D. Del. 1966); *Baldwin-Lima-Hamilton Corp. v. Tatnall Measuring Sys. Co.*, 169 F. Supp. 1, 24-25 (E.D. Pa. 1958).

could be material only if it "concealed a disqualifying fact or hindered the discovery of a disqualifying fact." *Id.* at 789.

If either of these materiality standards were applied here, the information regarding past relationships between the declarants and the applicant would not be deemed material to the patentability of the invention claimed in the '398 patent. There is no evidence, let alone "clear, unequivocal, and convincing" evidence, *id.* at 772, that knowledge of those past relationships would have had the natural tendency of influencing the PTO to issue a rejection. Indeed, the Federal Circuit acknowledges the reality that it is normal practice "for the inventor to recommend, and even contact, his own colleagues or people who are, or who have been, affiliated with his employer and to submit declarations from such people," App. at 26a, suggesting that the PTO, when reviewing a declaration, routinely assumes that the declaration is from an individual known to the patent applicant.

B. The Federal Circuit's Intent Standard

The Federal Circuit's sliding scale standard for intent, which permits a finding of intent to deceive based only on evidence of a negligent non-disclosure of information the court deems highly material, has no basis in this Court's decisions or in its guidance in other substantive areas with an intent inquiry. Indeed, this Court has applied the inequitable conduct doctrine only once—in *Precision*—when the patentee knew about the relevant fraudulent conduct and "chose to act in disregard of the public interest," *Precision*, 324 U.S. at 816, by exploiting rather than reporting the fraud. Moreover, the Federal Circuit's intent standard is inconsistent with the malevolent intent standard that various

courts have used in applying the unclean hands doctrine[11] or in establishing fraud.[12] In none of these cases—covering many different areas of law—has this Court ever endorsed the view that intent would be judged on a sliding scale, with mere negligence sufficient in cases of high materiality.

V. The Federal Circuit's Inequitable Conduct Law Is Inconsistent With Settled Principles Governing Inherent Judicial Power and Administrative Law

In recognizing the power of federal courts to refuse enforcement of patents based on misconduct before the PTO, this Court invoked "the equitable maxim that 'he who comes into equity must come with clean hands,'" which is a "self-imposed ordinance" of the federal courts. *Precision*, 324 U.S. at 814. Federal courts possess such inherent equitable powers "to prevent abuses, oppression, and injustice," *Gumbel v. Pitkin*, 124 U.S. 131, 144 (1888), but this Court has employed a "traditionally cautious approach" to permitting federal courts' exercise of their "inherent equitable power." *Grupo Mexicano de Desarrollo, S.A. v. Alliance Bond Fund, Inc.*, 527 U.S. 308, 329 (1999). This approach is reflected in the field of copyright law, where federal courts recognize an inherent equitable power to refuse enforcement of intellectual property rights based on

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[11] *See Dollar Sys., Inc. v. Avcar Leasing Sys., Inc.*, 890 F.2d 165, 173 (9th Cir. 1989) (affirming district court's finding that "grossly negligent" conduct "did not rise to the level of misconduct necessary for the application of the unclean hands doctrine" because "[b]ad intent is the essence of the defense of unclean hands"); *A.H. Emery Co. v. Marcan Prods. Corp.*, 389 F.2d 11, 18 n.4 (2d Cir. 1968); *Eresch v. Braecklein*, 133 F.2d 12, 14 (10th Cir. 1943).

[12] *See United States v. U.S. Gypsum Co.*, 438 U.S. 422, 435 (1978); *Reilly v. Pinkus*, 338 U.S. 269, 276 (1949); *Dunbar v. United States*, 156 U.S. 185, 194 (1895).

fraud upon the agency but apply the doctrine "only rarely, when the [rightholder's] transgression is of serious proportions." 4 MELVILLE B. NIMMER & DAVID NIMMER, NIMMER ON COPYRIGHT § 13.09[B], at 13-310 (2006); *see also, e.g., Original Appalachian Artworks, Inc. v. Toy Loft, Inc.*, 684 F.2d 821, 828 (11th Cir. 1982); *Santrayll v. Burrell*, 993 F. Supp. 173, 176-77 (S.D.N.Y. 1998).

The inequitable conduct standards applied in this case reflect that Federal Circuit jurisprudence has dramatically departed from the traditional approach in this area. As previously mentioned, only once has this Court found cause to hold a patent unenforceable because of inequitable conduct before the administrative agency. But as of 1988, a study by the American Intellectual Property Law Association estimated that 80% of all patent infringement cases included charges of inequitable conduct.[13] This flood of inequitable conduct allegations is driven by the expansion of the inequitable conduct doctrine by the federal courts, as well as the uncertainty surrounding the doctrine. The result has been circuit splits and conflicts with this Court's precedents and with PTO practice.

An aggressive use of inherent judicial power is particularly inappropriate where a court is attempting to police the integrity of information submitted to an

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[13] Ad Hoc Committee on Rule 56 and Inequitable Conduct, American Intellectual Property Law Association, *The Doctrine of Inequitable Conduct and The Duty of Candor in Patent Prosecution: Its Current Adverse Impact on the Operation of the United States Patent System*, 16 AIPLA Q.J. 74, 75 (1988); *see also* Katherine Nolan-Stevaux, *Inequitable Conduct Claims in the 21st Century: Combating the Plague*, 20 BERKELEY TECH. L.J. 147, 163-64 (2005) (describing an empirical study that showed that 75% of inequitable conduct charges were found by the courts to be of no merit).

administrative agency. It is fundamental that issues concerning administrative process are particularly within the competence and expertise of federal agencies, and that the courts should permit agencies to be masters of their own procedures. *See Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 524-25 (1978). In this case, the Federal Circuit's inequitable conduct rules directly regulate both the amount of information that must be disclosed to the agency and the penalties for non-compliance. These are precisely the sort of matters that this Court has held *should* be left to the agency, with limited intervention from courts exercising inherent common law powers.

Moreover, this Court has made clear that it is the administrative agency's "responsibility to police fraud consistently with the Agency's judgment and objectives." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001). Indeed, for other administrative agencies, the Court has been willing to enforce an administrative order even though the beneficiary of the order committed perjury during the administrative proceedings. *See ABF Freight Sys., Inc. v. NLRB*, 510 U.S. 317 (1994).

Far from reinforcing the PTO's authority to police the integrity of its own proceedings, the Federal Circuit doctrine has displaced the agency-created standards and procedures. The Federal Circuit has now repeatedly held that, in judging materiality, federal courts are *not* constrained by the PTO's attempt through administrative rulemaking to define a more narrow standard of materiality than the one established in judicial caselaw. *See, e.g., Digital Control*, 437 F.3d at 1316 (stating that the "reasonable examiner" standard and the Federal Circuit's caselaw interpreting that standard "were

not supplanted by the PTO's adoption of a new Rule 56").[14] So dominant have courts become in this area that the PTO has now ceded to the courts primary responsibility for determining whether frauds or misrepresentations have occurred in its own proceedings.[15]

VI. The National Academies of Science and Engineering Have Endorsed Abolition or Reform of the Inequitable Conduct Doctrine

In 2004, the National Research Council of the National Academies of Science and Engineering released a report calling for various reforms of the current patent system. *See* A Patent System, *supra*. The report was produced by a committee of eminent lawyers, economists, legal academics, and corporate executives, and was funded by a broad cross-section of government agencies, foundations, and private corporations. This distinguished committee endorsed certain concrete proposals "to ensure the vitality and improve the functioning of the patent system," *id.* at 5 (executive summary) and specifically recommended "the elimination of the inequitable conduct doctrine or changes in its implementation," finding it imposes high costs in

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[14] To confirm the existing conflict between the PTO and the Federal Circuit, this Court could call for the views of the Solicitor General (CVSG)—an action this Court has increasingly used in evaluating certiorari petitions in patent cases.

[15] *See* PTO, Notice of Proposed Rulemaking, Duty of Disclosure, 56 Fed. Reg. 37321, 37323 (Aug. 6, 1991) (stating that the PTO "generally will not comment on duty of disclosure issues" and will exercise its authority to reject a patent application during the normal *ex parte* examination process "only in the most egregious and clear cases, *e.g.*, where there is a final court decision that inequitable conduct has occurred").

litigation and yet has "limited deterrent value," *id.* at 123.[16]

The National Academies of Science and Engineering singled out for criticism the practice of inferring "intent from the materiality of the information that was withheld." *Id.* This case involved such an inference, and the court applied the inference as a matter of law on summary judgment. Similarly, the uncertainty and the litigation burden cited by the National Academies of Science and Engineering also exist in this case. The decision below opens a new vein of inequitable conduct litigation—past employment relationships between declarants and assignees (and arguably licensees and other similar entities), other professional connections, and perhaps even friendships among the relevant parties, will now be fertile ground for inequitable conduct allegations. Even where, as in this case, the PTO showed no interest in obtaining such information about the declarants, a court can still find, 15 years after the fact, that the patent applicant intentionally deceived the PTO by failing to disclose tangential information that had no bearing on the patentability of the claimed invention.

The report also stressed that many other remedies exist for unethical conduct before the PTO. *Id.* at 122-23. Thus, narrowing the inequitable conduct doctrine to its traditional limits could "increase predictability of patent dispute outcomes and reduce the cost of litigation without substantially affecting the underlying principles that [this

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[16] The inequitable conduct doctrine has been widely criticized. *See, e.g.*, P.M. Janicke, *Do We Really Need So Many Mental and Emotional States in United States Patent Law?* 8 TEX. INTELL. PROP. L.J. 279 (2000); J.F. Lynch, *An Argument for Eliminating the Defense of Patent Unenforceability Based on Inequitable Conduct*, 16 AIPLA Q.J. 7 (1988); C.M. McMahon, *Intent to Commit Fraud on the USPTO: Is Mere Negligence Once Again Inequitable?* 27 AIPLA Q.J. 49 (1999).

aspect] of the enforcement system [was] meant to promote." *Id.* at 117-18.

CONCLUSION

For the reasons stated, this petition for a writ of certiorari should be granted.

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Ferring B.V.

APPENDIX

APPENDIX A - DECISION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

United States Court of Appeals for the Federal Circuit

05-1284

FERRING B.V. and AVENTIS PHARMACEUTICALS, INC.,

Plaintiffs-Appellants,

v.

BARR LABORATORIES, INC.,

Defendant-Appellee.

DECIDED: February 15, 2006

Before NEWMAN, MAYER, and DYK, Circuit Judges.

Opinion for the court by Circuit Judge DYK. Dissent by Circuit Judge NEWMAN.

DYK, Circuit Judge.

Ferring B.V. ("Ferring") and Aventis Pharmaceuticals, Inc. ("Aventis") brought suit against Barr Laboratories, Inc. ("Barr") for infringement of Ferring's patent, U.S. Patent No. 5,407,398 (filed Dec. 17, 1985) ("'398 patent"). Barr moved for summary judgment, arguing

that the '398 patent was unenforceable due to inequitable conduct and, alternatively, that Barr did not infringe the '398 patent. The district court granted summary judgment on both grounds. We affirm the district court's grant of summary judgment on the ground that the patent is unenforceable due to inequitable conduct, and we do not reach the issue of infringement.

BACKGROUND

Ferring patented a medicinal compound and a method of administering said compound. Specifically, claim one of Ferring's '398 patent (the independent composition claim) claimed an "antidiuretic composition for humans comprising a gastrointestinally absorbable, antidiuretically effective, amount of [the peptide] 1-deamino-8-D-arginine vasopressin and a pharmaceutically acceptable carrier in solid oral dosage form for absorption in the gastrointestinal tract of said humans." '398 patent at col.4 l.23-29. 1-deamino-8-D-arginine vasopressin and other compounds were known in the art to prevent the diuretic symptoms associated with diabetes when they were absorbed through the walls of the patient's mouth via a dissolving tablet, or through the patient's nasal passage via a liquid spray or plastic tube. However, such modes of administering the medicine proved cumbersome and time-consuming. Therefore, the claimed solid oral dosage form of the compound and method of administering it were thought to be an improvement over the prior art, because the medicine was designed to be simply swallowed and absorbed through the gastrointestinal tract. As the inequitable conduct claim arises from the prosecution history of the '398 patent, we will begin there.

I

Appendix A

On December 17, 1985, Hans Vilhardt and Helmer Hagstam filed an application for the '398 patent.[1] On May 28, 1986, Vilhardt and his counsel appeared at a preliminary interview conducted by Examiners Moyer and Stone at the Patent and Trademark Office ("PTO"). At the interview, the examiners discussed certain prior art references, including U.S. Patent No. 3,497,491 (filed Sept. 14, 1967) ("'491 patent" or "Zaoral patent"). Ferring was the exclusive licensee of the '491 patent until its expiration in 1987. The '491 patent taught, for antidiuretic purposes, that "1-deamino-8-D-arginine vasopressin" "may be used ... for the parenteral, peroral, intranasal, subcutaneous, intramuscular, or intravenous application." '491 patent at col.3 l.15-23, col.5 l.15-20 (emphasis added). The examiners were concerned that the '491 patent's disclosure of the "peroral" application of the peptide may have suggested the oral administration of the peptide for gastrointestinal absorption. Vilhardt argued that the term "peroral" as used in the '491 patent did not teach the oral administration of the peptide for gastrointestinal absorption, but rather for absorption through the walls of the mouth. As the examiners were not entirely convinced, they "suggested that applicants obtain evidence from a non-inventor" to support their interpretation of the term "peroral." J.A. at 3460 (emphasis added).

In response, on June 12, 1986, Vilhardt, through his counsel, submitted four declarations including two from

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[1]Inventors Vilhardt and Hagstam had been employed by Ferring and, in 1984, they assigned all of their prospective rights to the '398 patent to Ferring. Prior to the prosecution at issue, the inventors had twice filed applications for their invention, and both times their application was rejected as anticipated or obvious over U.S. Patent No. 3,497,491.

Vilhardt himself, one from a Dr. Myron Miller, and one from a Dr. Paul Czernichow. These declarations each relayed the writer's scientific belief that the term "peroral" in the '491 patent meant that the compound could be administered "through the mouth," but only for absorption through the cheek of the mouth or under the tongue. However, the declarations failed to disclose that Czernichow had been receiving research funding from Ferring from 1985-86.[2] Specifically, Czernichow received research funding to conduct a clinical investigation relating to a particular drug (DDAVP) preparation.

Despite the declarations, on November 13, 1986, the examiners rejected certain claims of the '398 patent as anticipated or obvious over the '491 patent. The rejection stated: "As Applicants are the exclusive licensee of the Zaoral ['491] patent, it is obviously expeditious for Applicants to argue that 'peroral' referred to in the ['491] patent referred only to sublingual or buccal routes, whereas the instant mode of administration excludes such routes as it involves absorption by the gastrointestinal tract." J.A. at 4390.

The inventors requested reconsideration after which a new examiner, Examiner Siegel, reaffirmed the rejections. Examiner Siegel stated that the '491 patent "clearly teaches orally administering said vasopressin," and that "oral administering of a drug . . . unambiguously means gastrointestinal absor[p]tion." J.A. at 3067.

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[2]Czernichow testified that he was not receiving funding from Ferring in June 1986, when he submitted his first declaration.

Appendix A

On November 13, 1987, the inventors appealed this rejection to the Board of Patent Appeals and Interferences ("Board"). On September 21, 1990, the Board accepted the declarants' view that, as a general rule, the "peroral" administration of a peptide would not be read in the art as suggesting the administration for gastrointestinal absorption. This is because peptides are normally "hydrolyzed in the stomach and it would be expected that their biological activities would be lost" prior to gastrointestinal absorption. J.A. at 3688. Thus, the '491 reference standing alone would not anticipate the applicant's claims regarding the peroral administration of the peptide. However, the Board determined that the applicants' claims were obvious over the '491 patent in light of an article written by Ivan Vavra in 1973. Vavra disclosed that 1-deamino-8-D-arginine vasopressin is structurally unique among peptides in that it does not degrade quickly. The Board found that although the term "peroral" may not usually suggest the gastrointestinal absorption of a peptide, the '491 patent's disclosure of the "peroral" administration of 1-deamino-8-D-arginine vasopressin, when combined with Vavra's disclosure that this peptide is slow to degrade, would render the applicant's claims obvious. The Board thus affirmed the examiners' obviousness rejection. However, because the examiners had not relied on the Vavra reference, the Board designated its decision as "a new rejection under the provisions of 37 C.F.R. [§] 1.196(b)," and explained that the applicant could "elect to have further prosecution before the examiner in response to the new rejection. . . ." J.A. at 3690.

The inventors opted to go back to the examiners. On November 21, 1990, the inventors submitted five more declarations to persuade the examiners that the Vavra reference would not, when read with the '491 patent, suggest

the gastrointestinal absorption of the peptide. As before, the inventors submitted declarations from Vilhardt, Miller, and Czernichow. They also submitted declarations from a Dr. Iain Robinson and a Dr. Tomislav Barth. Each of these declarations explained why, in the declarant's own professional judgment, the Vavra reference did not suggest that the peptide could be absorbed gastrointestinally. Just as before, the inventors did not inform the examiners that Czernichow had been receiving funds from Ferring.[3] This time, however, they also failed to inform the examiners that Robinson (one of the new declarants) had been Ferring's pre-clinical research director from 1985-1986 and a paid consultant for Ferring from 1986-1989. While Robinson was the research director at Ferring, Ferring was funding Vilhardt's research involving the peptide at issue. The inventors also did not disclose that Barth (another new declarant) worked on several projects funded by Ferring between 1984 and 1987. Barth also worked intermittently with Vilhardt on some small projects between 1988 and 2000, although it is unclear from Barth's testimony whether this research was funded by Ferring. Neither Robinson's nor Barth's declarations was accompanied with a Curriculum Vitae ("CV"). Czernichow's declaration did include an extensive CV. However, it did not mention his research with Ferring.

Vilhardt communicated with each of these declarants before their declarations were submitted to the PTO. Vilhardt also sent Barth a "draft declaration." While it is unclear exactly what was contained in the draft declaration,

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[3]It is unclear from the record whether Czernichow was receiving research funding at the very time he drafted his second declaration.

Vilhardt admitted that he gave Barth "some lines," telling him "what he should describe in the affidavit." J.A. at 5544. Vilhardt also sent Robinson a "draft declaration."

In sum, four of the five declarations submitted to the PTO in 1990 were written by scientists who had been employed or had received research funds from Ferring, and Vilhardt participated in the drafting of two of the four declarations submitted by non-inventors. The examiners were not otherwise made aware of the Ferring connections. After these declarations were submitted, the examiners allowed the previously rejected claims, and the '398 patent issued on September 10, 1991. The PTO did not provide any explanation for its allowance.

II

Ferring exclusively licensed the right to market and sell its patented antidiuretic compound to Aventis[4]. In July 2002, Barr filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration, seeking approval to market a generic version of the compound at issue. In connection with its ANDA, Barr filed a so-called "paragraph IV certification," which is a statement that any relevant patents to the generic compound are either invalid or will not be infringed. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2000). Barr's paragraph IV certification claimed that the

[4]The salt form of 1-deamino-8-D-arginine vasopressin, "DDAVP," is the actual product at issue here. Ferring and Barr disagree as to whether DDAVP is covered by the '398 patent. Because our opinion is confined to the inequitable conduct issue, we do not reach Barr's non-infringement claim, which would require us to resolve whether DDAVP is covered by the patent.

'398 patent was invalid. In response, Ferring filed an infringement action against Barr pursuant to 35 U.S.C. §271 (e)(2). Barr moved for summary judgment based on inequitable conduct and non-infringement. The district court granted summary judgment to Barr on both grounds. On the issue of inequitable conduct, the district court found:

> The undisputed evidence in this case supports the finding of inequitable conduct by the patentee and its agents and the grant of summary judgment. The reluctance of the PTO to issue the '398 patent was evident. Each affidavit submitted in support of its issuance was thus highly material to the prosecution history. That three of the challenged declarations were submitted after several iterations of rejected attempts to obtain the patent's issuance speaks loudly as to motive and intent. While credibility determinations from a courtroom observation may at times be necessary on the issue of intent, here, the entire record presents clear and convincing evidence of an intent to mislead the examiners, even viewing the evidence, as it must be viewed, in the light most favorable to Plaintiff. The submission of the Czernichow and Robinson declarations, and to a lesser extent that of Barth, support a finding of intent to mislead the PTO.

J.A. at 18. The court specifically found that "it must have been clear to Dr. Vilhardt at the preliminary meeting with the examiner that a non-inventor affidavit was sought for purposes of obtaining objective evidence that the invention

was not anticipated by the prior art or obvious." J.A. 16 (emphasis added). Ferring and Aventis timely appealed.

DISCUSSION

Appellants argue that the district court erred in granting summary judgment to Barr on both the issues of inequitable conduct and infringement. Because we find that the district court properly granted summary judgment to Barr on the inequitable conduct ground, we do not reach the infringement issue.[5]

"Inequitable conduct occurs when a patentee breaches his or her duty to the PTO of 'candor, good faith, and honesty.'" Warner-Lambert Co. v. Teva Pharms. USA, Inc., 418 F.3d 1326, 1342 (Fed. Cir. 2005) (quoting Mollins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995)). While inequitable conduct includes affirmative misrepresentations of material facts, it also arises when the patentee fails to disclose material information to the PTO. Id.; Pharmacia Corp. v. Par Pharm., Inc., 417 F.3d 1369, 1373 (Fed. Cir. 2005). "The inequitable conduct analysis is performed in two steps comprising 'first, a determination of whether the withheld reference meets a threshold level of materiality and intent to mislead, and second, a weighing of the materiality and intent in light of all the circumstances to determine whether the applicant's conduct is so culpable that the patent should be held unenforceable.'" Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1362-63

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[5] See, e.g., GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1275 (Fed. Cir. 2001) (finding infringement issues moot after patent was deemed unenforceable due to inequitable conduct).

(Fed. Cir. 2003) (quoting Purdue Pharma L.P. v Boehringer Ingelheim GMBH, 237 F.3d 1359, 1366 (Fed. Cir. 2001)). The predicate facts must be proven by clear and convincing evidence. Id. at 1362. "While our precedent urges caution in the grant of summary judgment respecting a defense of inequitable conduct, summary judgment is not foreclosed." Paragon Podiatry Lab., Inc. v. KLM Labs., Inc., 984 F.2d 1182, 1190 (Fed. Cir. 1993); see also Digital Control Inc. v. The Charles Machine Works, -- F.3d --, slip op. at 6 (Fed. Cir. 2006) ("Determining at summary judgment that a patent is unenforceable for inequitable conduct is permissible, but uncommon.").

I

We first consider the district court's determination that there were no genuine issues of material fact with respect to materiality and intent. Our review in this respect is without deference. Dayco Prods., 329 F.3d at 1362-63.

A. Materiality

For patent applications that have been prosecuted prior to 1992, we have held that "[i]nformation is deemed material if there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent." Li Second Family L.P. v. Toshiba Corp., 231 F.3d 1373, 1379 (Fed. Cir. 2000) (quoting 37 C.F.R. § 1.56 (1989)); Syntex (U.S.A.) LLC v. Apotex, Inc., 407 F.3d 1371, 1384 (Fed. Cir. 2005).[6] We have made clear that

[6]Although the PTO amended the language of 37 C.F.R. § 1.56 in 1992, we have continued to use the pre-1992 language regarding materiality for evaluating patents that were prosecuted before the

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examiners have broad authority to request information that they deem relevant to the issue of patentability. Star Fruits S.N.C. v. United States, 393 F.3d 1277, 1283 (Fed. Cir. 2005). In response to requests from examiners, applicants frequently submit supporting declarations. Given the ex parte nature of proceedings before the PTO, it is especially important that the examiner has all the information needed to determine whether and to what extent he should rely on declarations presented by the applicant.

The general law of evidence has long recognized that the testimony of any witness may be rendered suspect by a past relationship with a party.[7] The pertinent rules for PTO examiners have specifically recognized this evidentiary principle, explaining: "Affidavits or declarations should be scrutinized closely and the facts presented weighed with

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amendment. See Dayco Prods., 329 F.3d at 1363-64. Prior to the amendment, the relevant portion of § 1.56 read: "information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." 37 C.F.R. § 1.56(a) (1991). See also Digital Control Inc, -- F.3d at --, slip op. at 7-12 (finding that "the new Rule 56 was not intended to replace or supplant the 'reasonable examiner' standard," and recognizing that the case law supports several standards of materiality).

[7]See United States v. Robinson, 530 F.2d 1076, 1079-80 (D.C. Cir. 1976) (finding a witness's past business transactions with a party significant in assessing the witness's credibility); Aetna Ins. Co. v. Paddock, 301 F.2d 807, 812 (5th Cir. 1962) (finding a witness's past financial affiliation with a party significant in assessing his credibility); see also 3A Wigmore, Evidence § 949, at 786 (Chadbourn rev. 1983) ("The relation of employment, present or past, by one of the parties, is also usually relevant.").

care. The affiant's or declarant's interest is a factor which may be considered, but the affidavit or declaration cannot be disregarded solely for that reason." J.A. at 5415 (The Manual of Patent Examining Procedure). As appellants concede, we have previously held that a declarant's prior relationships with the patent applicant may be material, and that failure to disclose such relationships to the examiner may constitute inequitable conduct. Refac Int'l, Ltd. v. Lotus Dev. Corp., 81 F.3d 1576, 1581-82 (Fed. Cir. 1996); Paragon, 984 F.2d at 1191-92.

In Refac, the PTO examiner rejected an application because it did not sufficiently enable one skilled in the art to make the invention. 81 F.3d at 1578. The examiner stated that a supporting affidavit by the co-inventor had very little probative value and was "self serving." Id. In response, the inventors suggested that they submit affidavits from people "other than the inventors" to support the sufficiency of the disclosure. Id. They then submitted affidavits from three individuals but failed to disclose that at least one of the individuals had worked for the inventors' company for a short eight-week period and was already familiar with the invention. Id. at 1580-81. We affirmed the district court's finding that this omission was material and supported a finding of inequitable conduct. Id. at 1581-82. In so doing, we found it particularly important that "[a]n examiner must be able to evaluate information in an affidavit in context, giving it the proper weight. . . ." Id. at 1583.

In Paragon, the examiner requested "disinterested third party" declarations and when the inventors submitted the declarations, they failed to disclose that one of the declarants owned stock in the assignee's company at the time of his declaration and had previously been a consultant for the company. 984 F.2d at 1191. The declarant also averred

in his declaration that he had not been "employed" by the assignee's company. Id. We decided not to "quibble about whether a 'consultant' is or is not 'employed' by a company," finding instead that the declarant was not "a 'disinterested' party in any recognized sense of the word." Id. at 1192. We then affirmed a finding of inequitable conduct based on omissions regarding the declarant's affiliations. Id.

Here, appellants argue that the Ferring affiliations of declarants Czernichow, Robinson, and Barth, were immaterial as a matter of law because (1) those affiliations supposedly did not bear directly on the critical assertion that each made in his declaration, meaning that the relationships were not the source of the information in the declarations, and (2) the declarants did not have a direct financial stake in the success of the patent.

Our jurisprudence does not suggest such a narrow view of materiality.[8] A witness's interest is always pertinent to his credibility and to the weight to be given to his testimony, and relevant interests are not limited to direct financial interests. Under Refac and Paragon, a declarant's past relationships with the applicant are material if (1) the declarant's views on the underlying issue are material and

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[8]Contrary to appellants' assertions, Juicy Whip v. Orange Bang, Inc., 292 F.3d 728 (Fed. Cir. 2002) did not limit the relevance of particular affiliations to those where the affiliation gave the declarant specialized knowledge relating to his declarations. Juicy Whip simply held that the substance of an affidavit may be immaterial where the facts asserted therein were undisputed. See id. at 744. There is no concession in this case that the declarants' views as to the meaning of the term "peroral" in light of the Vavra reference were undisputed during prosecution.

(2) the past relationship to the applicant was a significant one. Here we think that each of these requirements was satisfied on the summary judgment record.

First, we agree with the district court that the declarations themselves were "highly material."[9] The Board itself relied on Czernichow's first declaration for the "general rule" that "peroral" would not be read by those in the art to suggest the gastrointestinal absorption of peptides. While the Board went on to reject the claims in light of the Vavra reference, Czernichow's declaration certainly advanced the applicants' argument. Moreover, the second set of declarations, which was plagued with even more undisclosed affiliations than the first set, was absolutely critical in overcoming the Board's obviousness rejection. The Board had found that the oral administration of 1-deamino-8-D-arginine vasopressin for gastrointestinal absorption was obvious in light of Vavra and the '491 patent. The sole purpose of the second set of declarations, therefore, was to show that the Vavra reference did not suggest that the peptide could be gastrointestinally absorbed. Towards this end, the declarations challenged the veracity of the Vavra reference and claimed that the reference was inapplicable to human gastrointestinal absorption. Not only were these declarations pivotal, they were essentially opinions that were

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[9] "While it is not necessary to cite cumulative prior art because it adds nothing to what is already of record (although it may be prudent to do so), one cannot excuse the submission of a misleading affidavit on the ground that it was only cumulative. Affidavits are inherently material, even if only cumulative. The affirmative act of submitting an affidavit must be construed as being intended to be relied upon. It is not comparable to omitting an unnecessary act." Refac, 81 F.3d at 1583 (emphasis added).

supported largely by the declarants' own scientific expertise and little else.

Second, we think it is equally clear that the summary judgment record shows that the past relationships were significant. Most significantly, one of the declarants, Robinson, was the research director at Ferring at the same time that Vilhardt was serving as a consultant to Ferring and was conducting his research on the very peptide at issue. Robinson was also a paid consultant for Ferring in the year immediately prior to his declaration. Czernichow was receiving research funding from Ferring at various points throughout the prosecution of the '398 patent and directly received funding before and after his 1986 declaration and continuing at least to the period immediately before his 1990 declaration. Finally, while Ferring may not have made payments to Barth personally, Ferring did fund Barth's research projects through Barth's employer. The privilege logs submitted by Ferring refer to all three of the declarants as "Ferring Consultants."[10]

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[10]Appellants argue that "Refac in fact held that, even after trial when credibility could be and was weighed, omitted disclosure of prior contacts that two PTO declarants [(Bullen and Cikra)] had had with the assignee of the patent in question did not suffice for materiality or intent, and did not constitute inequitable conduct." Ferring's Br. at 31. This is a misrepresentation of Refac's holding. There was no issue on appeal in Refac as to whether the omitted disclosure of the prior contacts of these two declarants was inequitable conduct. Our opinion simply described the district court's opinion. 81 F.3d at 1579. Even the district court's holding regarding these two declarants is not pertinent here because these declarants had no employment or financial connection with the inventors. Id.

These relationships were not isolated, nor were they confined to the distant past. The declarants clearly had ongoing and mutually beneficial relationships with Ferring during the prosecution of the '398 patent. In particular, Robinson's prior position as Ferring's research director and his subsequent consultant work for Ferring were extremely significant affiliations. The declarants were not disinterested. See Refac, 81 F.3d at 1581 (finding that "[i]t would surely have been important for the examiner, and any reasonable examiner, to know of Jones's [(the declarant)] association with Lanpar [(the inventor's company)]").

Despite appellants' assertions that the identity of the declarants was completely irrelevant to the examiners, the actual record made on summary judgment demonstrates otherwise. Indeed, it shows that the background, at least of the declarants Robinson and Czernichow, was not only material but was highly material. The examiners specifically requested "non-inventor" affidavits. Moreover, the examiners expressly stated that they were concerned about the objectivity of those trying to distinguish the '491 patent from the '398 patent. In their 1986 rejection, the examiners stated: "As Applicants are the exclusive licensee of the Zaoral ['491] patent, it is obviously expeditious for Applicants to argue that 'peroral' referred to in the patent referred only to sublingual or buccal routes, whereas the instant mode of administration [in their new patent] excludes such routes as it involves absorption by the gastrointestinal tract." J.A. at 4390. The examiners were thus keenly aware of the fact that Ferring was the exclusive licensee of the '491 patent, which was soon to expire, and had an interest in convincing the PTO that the application described an invention not disclosed in the '491 patent. The examiners treated Ferring and the applicants as one and the same. Based

on the examiners' request for non-inventor affidavits and their subsequent comments, it is clear from the summary judgment record that the examiners were concerned about the objectivity of those providing declarations and their relationship to Ferring, and that they communicated this concern to the applicants.

Under such circumstances, the applicant is on notice as to the materiality of information regarding the declarants' ties to Ferring. Of particular relevance here, we found in Refac that an examiner's characterization of the inventor's affidavit as "self-serving" put the inventors "on notice . . . that affidavits from disinterested persons were needed in order to overcome the substantive ground of the rejection." Id. at 1581-82 (emphasis added). Here, on summary judgment the district court was correct to conclude as a matter of law that the examiners' request for non-inventor declarations was for declarations from individuals without intimate ties to the inventors or Ferring itself. The court could conclude from the record as a matter of law that this concern was pertinent to the further affidavits submitted following remand by the Board since the central concern was still the '491 patent as prior art whether alone or in combination with the Vavra reference.

Finally, on the issue of materiality, appellants argue that they could have, at trial, presented evidence to raise a fact issue concerning either the significance of the experts' views or the significance of the past relationships. But the appellants presented no such contrary evidence in response to the summary judgment motion. As we discuss below in connection with the issue of intent, the appellants cannot raise a genuine issue of material fact by speculating as to what evidence might have been introduced at trial.

Thus, the district court correctly determined that the undisputed facts established a threshold showing of materiality; indeed, the record established that the undisclosed information at least in the aggregate was highly material as a matter of law.

B. Intent

Even if an omission is found to be material, the omission must also be found to have been made with the intent to deceive. "[M]ateriality does not presume intent, which is a separate and essential component of inequitable conduct." GFI, Inc., 265 F.3d at 1274 (quoting Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 552 (Fed. Cir. 1990)). However, "[i]ntent need not, and rarely can, be proven by direct evidence." Merck & Co., Inc. v. Danbury Pharmacal, Inc., 873 F.2d 1418, 1422 (Fed. Cir. 1989). We recently held in Bruno Indep. Living Aids, Inc. v. Acron Mobility Servs., Ltd., 394 F.3d 1348 (Fed. Cir. 2005), that "in the absence of a credible explanation, intent to deceive is generally inferred from the facts and circumstances surrounding a knowing failure to disclose material information." Id. at 1354 (emphasis added) (finding that where the patentee "has not proffered a credible explanation for the nondisclosure . . . an inference of deceptive intent may fairly be drawn in the absence of such an explanation"). Similarly, in Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253 (Fed. Cir. 1997), we made it clear that "a patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish 'subjective good faith' sufficient to prevent the drawing of

an inference of intent to mislead." Id. at 1257.[11] Contrary to Ferring's argument, the question of intent is directed to the applicant's intent, not to the intent of the declarants. Thus, that the declarants may have had no intent to deceive is entirely irrelevant. The question is whether the applicant (here Vilhardt) had such an intent.

We need not in this case attempt to lay down a general rule as to when intent may be or must be inferred from the withholding of material information by an applicant. Suffice it to say that we have recognized, in cases such as Paragon, that summary judgment is appropriate on the issue of intent if there has been a failure to supply highly material information and if the summary judgment record establishes that (1) the applicant knew of the information; (2) the applicant knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding. See Bruno Indep. Living Aids, 394 F.3d at 1354; Critikon, Inc., 120 F.3d at 1257. Here, all three conditions are satisfied.

First, Barr established that Vilhardt knew of significant past relationships of at least two of the declarants. Vilhardt was aware that Robinson was Ferring's pre-clinical research director while Vilhardt was serving as a consultant to Ferring researching the very peptide at issue. Robinson served as Vilhardt's contact at Ferring during this time.

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[11] See also Warner-Lambert Co., 418 F.3d at 1346; Pharmacia, 417 F.3d at 1373; Semiconductor Energy Lab. Co. v. Samsung Elec. Co. 204 F.3d 1368, 1375 (Fed. Cir. 2000); cf. Dayco Prods., Inc., 329 F.3d at 1367 ("Intent to deceive cannot be inferred simply from the decision to withhold the reference where the reasons given for the withholding are plausible.").

Vilhardt was also aware of Bath's affiliation with Ferring. Although he testified that he did not believe that Barth was a Ferring "consultant," he indicated that he was aware of a working arrangement between Ferring and Barth's employer under which Ferring had funded support for Barth's research. Additionally, as Ferring notes in its brief, "[b]etween 1988 and 2000, [Barth] worked a month most years in Dr. Vilhardt's laboratory for which he was paid a maintenance stipend." Ferring's Br. at 28.[12]

As to the second question—Vilhardt's knowledge of the materiality of the information—it is undisputed that the examiners were concerned about the identity of the affiants and that Vilhardt was aware of this concern since he was present at the interview with the examiners when the concern was expressed. A similar factual scenario supported a finding of intent in Refac, 81 F.3d at 1580. There, the examiner indicated that an affidavit by the co-inventor on a particular issue was "self-serving." We concluded that "[g]iven what the examiner characterized as the self-serving nature of [the inventor's] affidavit, [the applicants] were on notice from the PTO that affidavits from disinterested persons were needed in order to overcome the substantive ground of the rejection." Id. at 1581-82 (emphasis added). We then upheld a finding of intent to mislead the PTO. Id. Similarly, the fact that the examiners here requested "non-inventor" affidavits and expressed concern about bias supports the district court's conclusion that Vilhardt was on notice that disinterested affidavits were necessary, and knew

[12]The record is unclear as to whether Vilhardt was aware of Czernichow's longstanding relationship with Ferring.

or should have known that the Ferring affiliations were material.

Finally, the appellants urge that there is potentially a credible explanation here for the withholding. The crux of appellants' argument is that there are possible benign explanations for the withholding and that evidence might have been developed at trial to support those theories. Thus, appellants assert that it was improper for the district court to grant summary judgment to Barr "without seeing or hearing from the accused Dr. Vilhardt," Aventis' Br. at 34, and complained that "Barr's counsel did not ask Dr. Vilhardt or any other declarant a single question which would bear on the issue of intent." Ferring's Br. at 30. We find this argument to be quite remarkable. On summary judgment, in order to create a genuine issue, the appellants bore the burden of submitting an affidavit from Vilhardt to contradict the movant's evidence of intent if they believed that testimony from Vilhardt would establish credible evidence for the withholding.[13] Appellants cannot create a genuine issue by suggesting that Vilhardt might have proffered favorable evidence at trial. As we said in Paragon, when the movant has "made a prima facie case of inequitable conduct by satisfying both elements thereof, the burden shift[s] to

[13]Appellants argue that the district court improperly made credibility findings concerning Vilhardt on summary judgment. Typeright Keyboard Corp. v. Microsoft Corp., 374 F.3d 1151, 1158 (Fed. Cir. 2004) (holding that in some circumstances, summary judgment may be inappropriate when the credibility of an affiant is drawn into question). Here however, appellants' argument is misplaced because Vilhardt's credibility was never in dispute. Credibility can only become an issue once a party offers a declarant's testimony in support or in opposition to summary judgment.

[the nonmovant] to come forward with evidence which would require reassessment of the validity of the defense." 984 F.2d at 1191.

Appellants' specific arguments fare no better. Appellants argue that Vilhardt, as a foreign scientist, was not familiar with patent prosecution, and therefore would not have known of "some obligation to disclose declarants' associations with Ferring." Aventis' Br. at 28. There is no record evidence supporting Vilhardt's lack of knowledge.[14] To the contrary, the summary judgment record compels the conclusion that Vilhardt was aware of his obligation. In executing his inventorship declaration, Vilhardt acknowledged his "duty to disclose information which is material to the examination of this application." J.A. 3455. Furthermore, Vilhardt was represented by counsel throughout the proceedings before the PTO.

Appellants also argue that "there was no reason for Dr. Vilhardt, a foreigner and non-lawyer, to have understood the examiner to be requesting declarations from persons with no relationship to Ferring." Aventis' Br. at 25. Here again, appellants offered nothing to support such an inference. As we have already discussed in Refac, once the examiner discounts an affidavit for bias, the applicant is deemed to be on notice that a disinterested affidavit is required. 81 F.3d at 1581-82. The evidence here indicates that the examiners previously discounted the opinions of those connected to Ferring because the examiners found Ferring to have a

[14]The situation here is quite different from that in In re Harita, 847 F.2d 801 (Fed. Cir. 1988), where the charge of intent to mislead was refuted by detailed explanations of the failure to disclose prior art by a Japanese patent agent unfamiliar with United States patent requirements.

substantial interest in the patent. Given the examiners' statements and the evidence that Vilhardt understood their request and played more than a bystander's role in obtaining the affidavits, one cannot reasonably infer that Vilhardt was simply unaware of the examiners' concerns or his duty to satisfy those concerns.

In short, appellants' argument concerning credible explanations consists entirely of speculation. Conclusory allegations and attorney arguments are insufficient to overcome a motion for summary judgment. Biotec Biologische Naturverpackungen GmbH & Co. KG v. Biocorp, Inc, 249 F.3d 1341, 1353 (Fed. Cir. 2001); Glaverbel Societe Anonyme v. Northlake Marketing & Supply, Inc., 45 F.3d 1550, 1562 (Fed. Cir. 1995) ("There must be sufficient substance, other than attorney argument, to show that the issue requires trial."). As we said in Paragon, "insupportable, [or] specious . . . explanations or excuses will not suffice to raise a genuine issue of fact." 984 F.2d at 1190. In order to raise a genuine issue of fact, a party must submit conflicting evidence in the form of an affidavit or other admissible evidence.[15]

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[15] Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248-49 (1986) (holding that once the movant properly supports its motion for summary judgment, the burden of production shifts to the nonmovant and it "may not rest upon the mere allegations or denials of [its] pleading, but . . . must set forth specific facts showing that there is a genuine issue for trial") (internal quotation marks omitted); Biocorp, Inc., 249 F.3d at 1353 ("The party opposing the [summary judgment] motion must point to an evidentiary conflict created on the record at least by a counter statement of a fact or facts set forth in detail in an affidavit by a knowledgeable affiant. Mere denials or conclusory statements are insufficient.") (quoting Barmag Barmer Maschinenfabrik AG v. Mach. Ltd., 731 F.2d 831, 836 (Fed. Cir. 1984)).

Appendix A

Far from there being a credible explanation for the withholding, there is evidence in the summary judgment record supporting a conclusion that the past relationships were deliberately concealed. Although Vilhardt (who was already known by the examiners to have an affiliation with Ferring) submitted a CV with his declaration which disclosed that he had previously been the Research Director at Ferring, Robinson's declaration came with no CV and no indication that he was recently Ferring's Research Director. Likewise, Barth's declaration was submitted with no CV. Unlike the others, Czhernichow's declaration was accompanied by an extensive CV. However, it failed to mention his research funding from Ferring. Under similar circumstances, we concluded that the omission of prior employment with the patentee supported a showing of intent. See Refac, 81 F.3d at 1581. So too Vilhardt initially stated that he had no contact with the declarants, but later admitted—when confronted with the privilege log referring to these individuals as Ferring consultants—that he had contacted each of the declarants and that he sent Barth and Robinson "draft declarations,"[16] thus suggesting a desire to conceal the extent of his involvement.

We conclude that the district court properly granted summary judgment on the issue of intent.

II

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[16]Barr's evidence that Vilhardt was involved in the drafting of the declarations consists of Vilhardt's own deposition testimony that he sent "draft declarations" to both Barth and Robinson, as well as statements by Czernichow and Barth indicating that they did not write all parts of their declarations.

Having found that there were no genuine factual disputes with respect to the issues of materiality and intent, we turn to the question whether the court properly weighed materiality together with intent to determine that the conduct was "inequitable." We review the district court's ultimate finding of inequitable conduct for abuse of discretion. See Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 876 (Fed. Cir. 1988); Paragon, 984 F.2d at 1191. The same standard applies to review of discretionary determinations where the district court rules on summary judgment. See Gen. Elec. Co. v. Joiner, 522 U.S. 142-43 (1997) (holding that the district court's exclusion of expert testimony made in the context of a summary judgment motion was reviewed for abuse of discretion while the existence of separate issues of fact were reviewed de novo).[17]

In evaluating the conduct here, we note again that the omitted affiliation with respect to Robinson in particular was highly material since Robinson had actually been employed by Ferring. So too there was not simply a single omission. Rather, there were multiple omissions over a long period of

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[17]See, e.g., Scholle Corp. v. Blackhawk Molding Co., Inc., 133 F.3d 1469, 1471 (Fed. Cir. 1998) (reviewing a district court's finding of equitable estoppel on summary judgment for abuse of discretion); Alternative Sys. Concepts, Inc. v. Synopsys, Inc., 374 F.3d 23, 31 (1st Cir. 2004) (reviewing a district court's finding of judicial estoppel on summary judgment for abuse of discretion); Nat'l Ass'n of Gov't Employees v. City Pub. Serv. Bd., 40 F.3d 698, 707 (5th Cir. 1994) (reviewing a district court's finding of laches on summary judgment for abuse of discretion); Booth v. Barber Transp. Co., 256 F.2d 927, 931 (8th Cir. 1958) (reviewing a district court's grant of specific performance on summary judgment for abuse of discretion).

time—a fact that heightens the seriousness of the conduct. See Refac, 81 F.3d at 1580, 1582 (finding that additional omissions, even if they do not themselves constitute inequitable conduct, can heighten the effect of the omission at issue). Here, by presenting five separate declarations to the examiners, the applicants appeared to have a broad consensus of scientific support to overcome the Vavra reference. In actuality, four of the five declarations were submitted by scientists with significant associations with the assignee itself. While we will never know how the examiners may have weighed the declarations differently, it seems clear to us that this stellar showing of support would have, at the very least, been tarnished. In view of all the circumstances, we cannot find that the district court abused its discretion in finding inequitable conduct.

In coming to this conclusion, we fully recognize that inventors often consult their colleagues or other persons skilled in the art whom they have met during the course of their professional life. Accordingly, when an inventor is asked to provide supportive declarations to the PTO, it may be completely natural for the inventor to recommend, and even contact, his own colleagues or people who are, or who have been, affiliated with his employer and to submit declarations from such people. Nothing in this opinion should be read as discouraging such practice. Rather, at least where the objectivity of the declarant is an issue in the prosecution, the inventor must disclose the known relationships and affiliations of the declarants so that those interests can be considered in weighing the declarations. This is not an onerous burden to place on any applicant.

Appendix A

CONCLUSION

For the foregoing reasons, the decision below is affirmed.

AFFIRMED

COSTS

No costs.

APPENDIX A - DECISION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

United States Court of Appeals for the Federal Circuit

05-1284

FERRING B.V.,

Plaintiff-Appellant,

and

AVENTIS PHARMACEUTICALS, INC.,

Plaintiff-Appellant,

v.

BARR LABORATORIES, INC.,

Defendant-Appellee.

NEWMAN, Circuit Judge, dissenting.

"Inequitable conduct" in patent practice means misconduct by the patent applicant in dealings with the patent examiner, whereby the applicant or its attorney is found to have engaged in practices intended to deceive or mislead the examiner into granting the patent. It is a serious charge, and the effect is that an otherwise valid and invariably valuable patent is rendered unenforceable, for the charge arises only as a defense to patent infringement.

As this litigation-driven issue evolved, the law came to demand a perfection that few could attain in the

complexities of patent practice. The result was not simply the elimination of fraudulently obtained patents, when such situations existed. The consequences were disproportionally pernicious, for they went far beyond punishing improper practice. The defense was grossly misused, and with inequitable conduct charged in almost every case in litigation, judges came to believe that every inventor and every patent attorney wallowed in sharp practice. This history was recently summarized as follows:

> As is known, about 20 years ago inequitable conduct was frequently pleaded as a defense to patent infringement; a patent that is "unenforceable" due to a finding of inequitable conduct is dead. The defense was so misused by alleged infringers that the Federal Circuit once called this defense a "scourge" on US patent litigation .... The famous Kingsdown seemed to put a stop to the defense of inequitable conduct. ...

Michael D. Kaminski, Effective Management of US Patent Litigation, 18 Intell. Prop. & Tech. L.J. 13, 24 (2006) (footnote omitted) (citing Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867 (Fed. Cir. 1988) (*en banc* in relevant part)).

My colleagues on this panel have regressed to that benighted era, rejecting the efforts of Kingsdown to bring objectivity to charges of inequitable conduct, instead reviving the culture of attack on inventor rights and attorney reputations based on inference and innuendo. My colleagues, endorsing several novel and unsupportable presumptions of wrongdoing, do injury to the reasonable

practice of patent solicitation, even as they defy the rules of summary judgment.

This is not hyperbole. Practitioners from an earlier era well recall the adverse impact on industrial innovation when patents were not a reliable support for commercial investment, based in part on the judicial belief that patents and their practice were seriously flawed. With invalidation of most of the patents that reached the courthouse, the contribution of a diminished patent incentive to the weakening of technology-based investment was a serious national concern, and the impact on the nation's commercial vigor was recognized by government as well as by the industrial and scientific communities. See Domestic Policy Review of Industrial Innovation, Final Report, Dep't of Commerce (1979). The formation of the Federal Circuit Court of Appeals was part of the nation's program to restore technology-based leadership with the aid of an effective patent system.

The Federal Circuit recognized that specious charges of inequitable conduct were a disincentive to technologic innovation, and in Burlington Indus. v. Dayco Corp., 849 F.2d 1418, 1422 (Fed. Cir. 1988) this court remarked that "the habit of charging inequitable conduct in almost every major patent case has become an absolute plague." The Federal Circuit understood the ease with which accused infringers could challenge the niceties of patent prosecution, for as the law stood it was irrelevant whether the examiner was in fact deceived, or whether the purported flaw in prosecution affected patentability, or whether the action was an intentional misrepresentation or at worst negligence, or whether the invention met the statutory requirements of

patentability.[1] Thus the Federal Circuit undertook to bring objective standards and reasoned perspective to the charge of inequitable conduct.

In Kingsdown, the Federal Circuit held that in order to invalidate a patent for inequitable conduct in obtaining the patent, there must be both a material misrepresentation and intent to deceive. The court established that it is necessary to consider all of the evidence including evidence of good faith, and that both materiality and deceptive intent must be proved by clear and convincing evidence. Kingsdown established that no longer would negligence alone support a holding of inequitable conduct. The Federal Circuit did not believe that inventors and patent attorneys are more or less virtuous than anyone else; they simply held that charges of deceptive action must be proved on objective standards, as the law requires for property-forfeiting charges under the common law. Experience shows that Kingsdown's simple changes in the law were an important contribution to restoration of the patent system as an incentive to industrial innovation, for this court has recognized that a "'patentee's oversights are easily magnified out of proportion by one accused of infringement.'" Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 939 (Fed. Cir. 1990) (quoting Pfizer, Inc. v. Int'l Rectifier Corp., 538 F.2d 180, 186 (8th Cir. 1976)).

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[1]For example, an inventor is required to provide the Patent Office with all prior art references known to the inventor that are "material to patentability"; if the inventor provided selected references, he was accused of inequitable conduct in the selection; and if he provided an entire search report, he was accused of burying the significant references. The inventor was also required to provide a one-sentence statement about each reference that he listed; much was made of whatever was and was not in that sentence.

Appendix A

Today my colleagues on this panel not only ignore Kingsdown and restore a casually subjective standard, they also impose a positive inference of wrongdoing, replacing the need for evidence with a "should have known" standard of materiality, from which deceptive intent is inferred, even in the total absence of evidence. Thus the panel majority infers material misrepresentation, infers malevolent intent, presumes inequitable conduct, and wipes out a valuable property right, all on summary judgment, on the theory that the inventor "should have known" that something might be deemed material. The panel majority, steeped in adverse inferences, holds that good faith is irrelevant and presumes bad faith. Thus the court resurrects the plague of the past, ignoring the Kingsdown requirements of clear and convincing evidence of a misrepresentation or omission material to patentability, made intentionally and for the purpose of deception. I respectfully, but urgently, dissent.

The Accused Conduct

The examiner, at an interview at which the inventor Dr. Vilhardt was present, asked for "non-inventor" affidavits on the meaning of "peroral" and its significance to the claimed invention, apparently in accordance with the PTO custom that an inventor's statements are not adequate.[2] The inventor strictly complied with this request, presenting statements of four distinguished scientists who were not inventors. The filing of the declarations of three of the affiants, Drs. Czernichow, Robinson, and Barth, is held by

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[2]An examiner later dismissed the requested declarations defining "peroral," stating that "such evidence is not necessary to construe the meaning of an ordinary term in the English language."

my colleagues to establish inequitable conduct simply because they did not state their past professional relationships with the applicant. These past affiliations are not clearly and convincingly material as a matter of law, and their omission does not establish clear and convincing evidence of deceptive intent as a matter of law.

Dr. Paul Czernichow was a world renowned pediatric endocrinologist, Professor of Pediatrics at the Hospital des Enfants-Malades, Paris, and had published 106 papers. The record states that Ferring had provided equipment used in a clinical trial that Dr. Czernichow had previously conducted at the hospital. He received no remuneration from Ferring for this trial, and was not paid for his affidavit. Although the majority makes much of his "extensive CV" that fails to mention the funding for the clinical trial, the majority fails to point out that 25 of the 28 pages of his CV list his publications, and the first 3 pages --where his qualifications, work experience and honors are listed -- are organized such that one would not expect partial funding for a research project to appear. The most reasonable inference, to which Ferring is entitled on summary judgment, is that Dr. Czernichow's relationship with Ferring was so remote as to not be worthy of a listing in his CV. Further, as my colleagues acknowledge, the summery judgment record contains no evidence that Dr. Vilhardt was aware of this prior relationship. Indeed, the only evidence on this issue is his answer upon being asked whether he knew whether Dr. Czernichow had been a Ferring consultant: "Not to my knowledge, no, but whether he had some kind of grant from Ferring I wouldn't know, but I never heard him described as a consultant."

Dr. Tomislav Barth was a Professor at the Academy of Sciences of the Czech Republic in the Department of

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Organic Chemistry and Biochemistry, with twenty-five years of experience in the fields of peptide biochemistry, metabolism, pharmacology and pharmacokinetics. The record states that Ferring had made research grants to the Czech Academy of Sciences, and that Dr. Barth worked on such projects, although he was not compensated by Ferring. Dr. Barth later did some experimental work for Ferring for "allowances and accommodation and costs," but he was not engaged in such work at the time of his declaration and was not paid for his affidavit. There is no evidence in the summary judgment record that Dr. Vilhardt was aware of this prior affiliation, apart from his speculation during questioning that "it is possible that Tomislav Barth, who was a sort of contact person between Ferring and the department - the academy, that he may have obtained a small fee for that. I don't know."

Dr. Myron Miller was the Chief of Geriatric Medicine at the Veterans Administration Medical Center in Syracuse, New York, and had published 111 scientific papers. The record shows no research or employment relationship with the applicant, and none is asserted. Dr. Miller submitted two declarations, one to define "peroral" and one concerning gastrointestinal absorption. He was not paid for these statements.

Dr. I.C.A.F. Robinson, a neurophysiologist and an expert in neurophysin chemistry, was at the time of his declaration the head of the Division of Molecular Neuroendocrinology at the National Institute for Medical Research in London; he held a doctorate in endocrinology from Oxford University and had published 161 scientific papers. Dr. Robinson worked for Ferring as director of pre-clinical research for one year from 1985-86, and as a paid occasional consultant until 1989. He too was not paid for his

statements, and by the time of his 1990 declaration, his consulting relationship with Ferring had ended. His declaration was not submitted in response to the examiner's request for "non-inventor" testimony in 1986; it was filed four years later, after the Board had affirmed the applicant's interpretation of "peroral" and entered a new rejection based on obviousness.

In short, the summary judgment record consists of declarations by four respected non-inventor scientists, three of whom had a scientific relationship with Ferring, and Dr. Vilhardt knew of only one of these affiliations -- Dr. Robinson's affiliation that was omitted from a declaration submitted after the relationship ended and four years after the examiner's request for "non-inventor" testimony. There is no evidence, or even an allegation, that any of these scientists had anything to gain or lose as a result of the issuance of the '398 patent. The finding of the panel majority that all of the affiants had "intimate ties" with the patentee is a mischaracterization, and the inference that their scientific opinions may be biased and were submitted with deceptive intent is a travesty. Further, such a charge of malfeasance cannot be decided adversely on summary judgment. See generally IV Wigmore on Evidence §1104 (3d ed. 1957) (every witness is in law assumed to be of normal moral character for veracity). There is simply no evidence of any intention to withhold these relationships; in fact, there is no evidence that Dr. Vilhardt even thought about whether or not to disclose these affiliations, much less that he made the deliberate decision to withhold material information from the PTO. Indeed, the professors' reputations are enough, on the face of their scholarship, to put into dispute the panel majority's summary judgment that they deliberately

concealed information that was important to the credibility of their affidavits.

Nonetheless, my colleagues, without inquiry or evidence, rule that deceptive intent must be inferred. The panel majority posits that the examiner was necessarily misled, and intentionally so, by the absence from their affidavits or curricula vitae of these relationships. The majority reaches this conclusion that clear and convincing evidence of materiality and intent are established, not upon considering and weighing the particular facts, but by adverse inference and presumption, on summary judgment. That is not the law of inequitable conduct, and it is not a reasonable application of any of the rules and protocols of evidence. See Baker Oil Tools, Inc. v. Geo Vann, Inc., 828 F.2d 1558, 1566 (Fed. Cir. 1987) ("If facts of materiality or intent are reasonably disputed, the issue is not amenable to summary disposition.")

Materiality

The issue here is not patent validity. The panel majority's finding of "materiality" is not substantive scientific materiality, but materiality per se of the relationship of the affiant to the applicant. There is no evidence or assertion that any of the affiants mis-defined "peroral" or presented a false opinion, or that the examiner was deceived by the information provided or not provided, or that these scientists provided misinformation or deliberate omissions in order to deceive the examiner. There is no evidence that the examiner, in asking for the views of "a non-inventor," was asking for or expecting the views of a stranger to the applicant.

The panel majority places great weight on the cases of Paragon Podiatry and Refac, where, on quite different

facts, the court found deliberate misrepresentation of the relationship of an affiant for deceptive purposes. These cases do not support the sweeping inference now applied. In Paragon Podiatry Lab., Inc. v. KLM Labs., Inc., 984 F.2d 1182, 1188 (Fed. Cir. 1993), materiality was not even at issue, the appellants having conceded that the examiner's request for a "disinterested third party" was not met by declarations from former consultants owning stock in the assignee's company. The affiants in Paragon not only failed to mention their stock ownership, but made the carefully worded statement that they were not "in the past employed by nor do I intend in the future to be employed by" the patentee. Id. at 1191. The court agreed that this "half-truth" was a material representation affecting the substantive content of the affidavits, and a deliberately artful contravention of the examiner's requirement. Id. at 1192. And in Refac International, Ltd. v. Lotus Development Corp., 81 F.3d 1576, 1579 (Fed. Cir. 1996) the relevant omitted material information was the declarant's prior experience with the invention. The declarant in Refac stated that "he could have written" the claimed computer program "from the written disclosures and flow chart shown in the drawing of [the] patent application," but failed to disclose that he "had worked with and reviewed documentation for the commercial embodiment of the invention" as an employee at the inventor's company, and had "recognized the flow chart as being essentially the same one" shown to him during training at the company. Id. at 1581. In Refac the Federal Circuit upheld the ruling of inequitable conduct, but also cautioned that finding "the omission of an aspect of one's employment history to be inequitable conduct might thus seem to be unduly severe, a heavy penalty for an arguably minor omission." Id. at 1584.

The panel majority misreads these cases as holding that prior employment history is always material if (1) the declarant's testimony is material and (2) the prior affiliation is "significant." Given the minimal affiliations found "significant" in this case, and the majority's holding that affidavits are always material, under the majority's rule the negligent omission of a past affiliation with an applicant will always be inequitable conduct. Neither Paragon nor Refac supports a broad rule that past affiliations are always material, whatever those affiliations and whatever their relation to the subject matter. To the contrary, these cases were analyzed and findings made in accordance with the Kingsdown criteria. Materiality requires evidence, as does deceptive intent. The panel majority's new per se rule is contrary to precedent, contrary to the rules of evidence, and contrary to reason, as is its assertion that the omitted relationships in this case are "highly material." See Hoffman-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1367 (Fed. Cir. 2003) ("This court has held that affirmative misrepresentations by the patentee, in contrast to misleading omissions, are more likely to be regarded as material.")

Paragon and Refac, like all precedent in this area, illustrate that questions of materiality and intent are factual in nature, and that per se inferences of bad faith and deception are improper. In Juicy Whip, Inc. v. Orange Bang, Inc., 292 F.3d 728 (Fed. Cir. 2002) this court agreed that the employment relationship of the declarant was not material to patentability, even though the applicant knew that the examiner had misunderstood the declaration as indicating that the declarant worked for a competitor. In Juicy Whip, as in Refac and Paragon, the court considered the particular facts with respect to both materiality and intent. In Refac, 81 F.3d at 1579, inequitable conduct was found in the

declarant's concealed prior experience with the invention, for his declaration stated that he "could have written" the claimed computer program from the specification alone. In Juicy Whip, in contrast, the misunderstood employment relationship was held by this court not to be material "to the issue before the examiner." 292 F.3d at 744. The panel majority errs in characterizing Juicy Whip as holding that "the substance of an affidavit may be immaterial where the facts asserted therein were undisputed," maj. op. at 12 n.8, for that was not the issue. Indeed, the court was "bothered" by the applicant's failure to correct the examiner's misunderstanding of the affiant's relationship, but concluded that this aspect was "immaterial to the issue before the examiner." 292 F.3d at 744.

Whether a past relationship between a declarant and the patent applicant is material to patentability depends on the facts of the relationship and the nature of the declaration. It is not per se material; and failure to explain the relationship is not per se deception. Indeed, it is rare that any scientist working in a specialized field would not have interacted professionally with other scientists and with the industries in that field. Such relationships do not warrant an inference of bias and deception. There must be evidence and analysis, not innuendo. Scientific integrity should not be impeached by per se rules without foundation.

On the facts of this case, where the declarants provided a text-book definition of "peroral" and their scientific opinion of the gastrointestinal behavior of the product, the past connections of these declarants do not establish per se material misrepresentation. "Information is material if a reasonable examiner would have considered it important to the patentability of a claim." Regents of Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1570, 1571 (Fed.

Cir. 1997) ("[U]nfounded speculation is not clear and convincing evidence of materiality.") The information in these affidavits was not shown to be incorrect. See Regents, 119 F.3d at 1570 ("There is no reason to believe that a reasonable examiner would have made any different decision . . . ."). The fundamentals of due process should not and cannot be replaced by non-evidentiary inferences and unfounded speculation.

Intent

In cases involving an omission of material information, "there must be clear and convincing evidence that the applicant made a deliberate decision to withhold a known material reference." Baxter Int'l, Inc. v. McGaw, Inc., 149 F.3d 1321, 1329 (Fed. Cir. 1998); see Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1574 (Fed. Cir. 1991) ("Conduct that requires forfeiture of all patent rights must be deliberate, and proved by clear and convincing evidence.") Thus, to prevail on summary judgment, Barr must establish that no reasonable jury could fail to find clear and convincing evidence of deceptive intent. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255-56 (1986).

In its motion for summary judgment, Barr put forward no evidence of deceptive intent. Nonetheless, the majority holds that clear and convincing evidence of deceptive intent may be inferred on summary judgment where the record establishes that the applicant "knew or should have known" that omitted information was material. The majority's ruling is directly contrary to Kingsdown, which held that even gross negligence may not establish deceptive intent, and that "the involved conduct, viewed in light of all the evidence, including evidence indicative of

good faith, must indicate sufficient culpability to require a finding of intent to deceive." 863 F.2d at 876; see Hewlett-Packard Co. v. Bausch & Lomb, Inc., 882 F.2d 1556, 1562 (Fed. Cir. 1989) ("[G]rossly negligent conduct may or may not compel an inference of an intent to mislead. Such an inference depends upon the totality of the circumstances . . . .") Of course, dishonest persons rarely confess to malfeasance, but the court goes too far in establishing such deceptive intent as a matter of law based on inference as to what an inventor "should have known." See Molins PLC v. Textron, Inc., 48 F.3d 1172, 1181 (Fed. Cir. 1995) ("the alleged conduct must not amount merely to the improper performance of, or omission of, an act one ought to have performed.... In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference").

The majority cites Bruno Indep. Living Aids and Critikon, Inc. to supports its proposition that the court has recognized

> in cases such as Paragon, that summary judgment is appropriate on the issue of intent if there has been a failure to supply highly material information if the summary judgment record establishes that (1) the applicant knew of the information; (2) the applicant knew or should have known of the materiality of the information, and (3) the applicant has not provided a credible explanation for the withholding. See Bruno Indep. Living Aids, 394 F.3d at 1354; Critikon, Inc., 120 F.3d at 1257.

Maj. op. at 17-18. That is an inaccurate summary of precedent. Paragon involved an affirmative misrepresentation, not an omission, and that case contains no suggestion of a "should have known" standard of materiality. See Paragon, 984 F.2d at 1192 (deceptive intent was established on summary judgment because the record only led to one conclusion upon considering all of the circumstances, including the fact that there was a "submission of deceptive, if not outright false, affidavits to the PTO"). And the court in Bruno Independent Living Aids, Inc. v. Acorn Mobility Servs. Ltd., 394 F.3d 1348 (Fed. Cir. 2005) did not grant summary judgment, but rather affirmed a district court's findings of deceptive intent on a standard of clear error, noting the high materiality of the omitted reference and the other particular facts of the case. The court's statement in Bruno Indep. Living Aids that "'an applicant who knew of the art or information cannot intentionally avoid learning of its materiality. . . it may be found that the applicant 'should have known' of that materiality,'" 394 F.3d at 1352 (quoting FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415 (Fed. Cir. 1987)), does not apply in this case, for there is no evidence or argument that Dr. Vilhardt deliberately avoided learning of the materiality of the undisclosed contacts. A fact finder could not find that the applicant had knowledge of materiality, upon consideration of all the circumstances of record.

Nor was there a mere failure to disclose a known material reference in Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1257 (Fed. Cir. 1997); the applicant in Critikon, Inc. also knowingly failed to disclose in reissue proceedings that invalidity and inequitable conduct were simultaneously being asserted as defenses in

litigation involving the very same patent. Id. at 1255. And although the court stated that "intent may be inferred where a patent applicant knew, or should have known, that withheld information would be material to the PTO's consideration of the patent application," id. at 1256, this proposition was supported solely by reference to Driscoll v. Cebalo, 731 F.2d 878, 885 (Fed. Cir. 1984), a case that was overruled *en banc* by Kingsdown on this very point. See Kingsdown, 863 F.2d at 876. Thus, this aspect of Critikon, Inc. has been correctly identified by practitioners as "bad law," both because it relies on the overruled Driscoll decision and because it is representative of a recent resurgence of the plague that Kingsdown had intended to cure.[3] See Lynn C. Tyler, Kingsdown Fifteen Years Later: What Does It Take to Prove Inequitable Conduct?, 13 Fed. Cir. B.J. 267, 276-78 (2004) (discussing the resurgence of Federal Circuit panel decisions that rely on precedent explicitly overruled by Kingsdown). Further, there is a wide gulf between a rule that intent "may" be inferred by a jury upon consideration of all the circumstances, in accordance with Kingsdown, and a rule that intent "must" be inferred as a matter of law against a party opposing summary judgment, based solely on a material omission, in violation of Kingsdown and in violation of the rules of summary judgment.

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[3]Indeed, the panel majority's citation to Digital Control Inc. v. Charles Mach. Works, ___ F.3d at —, 2006 U.S. App. LEXIS 2991, slip op. at 7-12 (Fed. Cir. Feb. 8, 2006) is a further indication of the court's departure from precedent concerning inequitable conduct. The court in Digital Control holds, in contradiction of precedent, that it will hold practitioners to the standard of the pre-1992 version of Rule 56 for patents prosecuted after 1992, even though that standard no longer exists. 2006 U.S. App. LEXIS 2991, at *10-19.

Appendix A

Although some recent panel decisions appear to have relied on precedent overruled by Kingsdown, such decisions cannot overrule an *en banc* decision of this court, or the numerous post-Kingsdown cases that have held fast to the requirement of clear and convincing evidence of both materiality and intent. See, e.g., Hoffmann-La Roche, 323 F.3d at 1361 ("the district court committed clear error in finding clear and convincing evidence of intent to deceive in the inventors' failure to disclose"); Allen Eng'g Corp. v. Bartell Indus., 299 F.3d 1336, 1351 (Fed. Cir. 2002) (rejecting argument that nondisclosed information was so material that its nondisclosure should infer an intent to deceive, "for even if [the applicant's] conduct amounted to gross negligence, this alone would not be sufficient to show the requisite intent"); Catalina Lighting, Inc. v. Lamps Plus, Inc., 295 F.3d 1277, 1289 (Fed. Cir. 2002) ("'intent to deceive can not be inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent'") (quoting Hebert v. Lisle Corp., 99 F.3d 1109, 1116 (Fed. Cir. 1996)); Jazz Photo Corp. v. Int'l Trade Comm'n, 264 F.3d 1094, 1110 (Fed. Cir. 2001) ("absence of a reference from the prosecution record does not prove deceptive intent; there must be evidence sufficient to show, clearly and convincingly, the intent to withhold material information in order to deceive or mislead the examiner"); Molins, 48 F.3d at 1181 ("the alleged conduct must not amount merely to the improper performance of, or omission of, an act one ought to have performed. Rather, clear and convincing evidence must prove that an applicant had the specific intent to accomplish an act that the applicant ought not to have performed, viz., misleading or deceiving the PTO"); Therma-Tru Corp. v. Peachtree Doors Inc., 44 F.3d 988, 996 (Fed. Cir. 1995) (intent to deceive or mislead should not be inferred from the

fact that information was not provided to the examiner); Halliburton Co. v. Schlumberger Tech. Corp., 925 F.2d 1435, 1443 (Fed. Cir. 1991)("As Kingsdown made abundantly clear, gross negligence alone does not compel the inference of intent to deceive. Gross negligence cannot elevate itself by its figurative boot-straps to an intent to mislead based on the identical factors used to establish gross negligence in the first instance unless all the facts and circumstances indicate sufficient culpability."); Allen Organ Co. v. Kimball Int'l, Inc., 839 F.2d 1556, 1567 (Fed. Cir. 1988) ("[M]ateriality does not presume intent, which is a separate and essential component of inequitable conduct.")

Numerous cases affirm the principle that inequitable conduct requires consideration of the record as a whole, including evidence of good faith. See, e.g., Warner-Lambert Co. v. Teva Pharms. USA, Inc., 418 F.3d 1326, 1348 (Fed. Cir. 2005) ("there is no bright line test for determining whether inequitable conduct occurred; each case must be assessed independently"); Semiconductor Energy Lab. Co. v. Samsung Elecs. Co., 204 F.3d 1368, 1383 (Fed. Cir. 2000) ("Under all the circumstances of record, the court did not seriously misjudge the import of the evidence . . . in reaching the conclusion that equity warranted rendering the patent unenforceable."); Upjohn Co. v. MOVA Pharm. Corp., 225 F.3d 1306, 1312 (Fed. Cir. 2000) ("Both materiality and intent to deceive must be proven by clear and convincing evidence."); Refac, 81 F.3d at 1584-85 (recognizing the importance of credibility findings in evaluating intent).

Heretofore, no case has found inequitable conduct based on omitted information when there was no evidence of intentional omission and not even circumstantial evidence of deceptive intent. The panel majority's holding that deceptive intent is established as a matter of law if the applicant

"should have known" that information might be material to patentability, further revives the "plague" of the past, with burdens that far outweigh any conceivable benefits.

Summary Judgment

The court not only creates a new rule of law, but faults the patentee for failing to provide, on the summary judgment record, evidence to respond to an unknown "should have known" per se rule that until now was absent from this law. It is improper, and unfair, to require nugatory evidence on a point that was not raised in the motion for summary judgment, and then to grant the motion because the balancing evidence was not there. The panel majority not only charges the inventor Dr. Vilhardt with at least negligence, but denies him the opportunity now to respond to the court's creative new ruling. Although in Therma-Tru Corp., 44 F.3d at 996, this court stated that the "theory of inferential culpability was definitively laid to rest in Kingsdown," if it is to be revived the inventor must be given the opportunity to support his good faith.

In Poller v. Columbia Broadcasting System, Inc., 368 U.S. 464 (1962), the Court cautioned against the grant of summary judgment when "motive and intent play leading roles," for:

> It is only when the witnesses are present and subject to cross-examination that their credibility and the weight to be given their testimony can be appraised. Trial by affidavit is no substitute for trial by jury which so long has been the hallmark of "even handed justice."

368 U.S. at 473. This court has often held similarly, for intent to deceive is a question of "the state of mind of one making representations," Kangaroos U.S.A., Inc., v. Caldor, Inc., 778 F.2d 1571, 1576 (Fed. Cir. 1985), a "factual matter rarely free from dispute," id. at 1577, and thus "rarely enabled in summary proceedings." Id.; see Monsanto Co. v. Bayer Bioscience N.V., 363 F.3d 1235, 1241 (Fed. Cir. 2004) ("It was therefore improper for the district court on summary judgment to infer an intent to deceive based on the court's conclusion that the declaration was false and that the explanation for the falsity was unpersuasive."); Copelands' Enters., Inc. v. CNV, Inc., 945 F.2d 1563, 1567 (Fed. Cir. 1991) ("As a general rule, the factual question of intent is particularly unsuited to disposition on summary judgment.")

For summary judgment of inequitable conduct there must be clear and convincing evidence of materiality and deceptive intent, even on the non-movant's view of the facts. In this case, credibility has been placed at issue. The panel majority improperly draws adverse inferences against the party opposing summary judgment, inferring (1) that when the examiner requested "non-inventor" declarations, he expected experts who had no relationship with Ferring; (2) that Dr. Vilhardt understood that to be the examiner's request; and (3) that when Dr. Vilhardt contacted these distinguished scientists and obtained their affidavits -- an act my colleagues characterize as "completely natural" -- he and Ferring deliberately concealed their past connections, with the intent to deceive the PTO. The Supreme Court has reiterated that "Summary judgment in favor of the party with the burden of persuasion, however, is inappropriate when the evidence is susceptible of different interpretations or inferences by the trier of fact." Hunt v. Cromartie, 526 U.S. 541, 553 (1999).

Appendix A

The panel majority holds that "to create a genuine issue, the appellants bore the burden of submitting an affidavit from Vilhardt to contradict the movant's evidence of intent." Maj. op. at 19. Setting aside the fact that the movant did not put forward any evidence of intent, there is no requirement in law that the non-movant submit an affidavit in opposing summary judgment. Ferring was free to rely on other more reliable forms of evidence, such as deposition testimony. See Fed. R. Civ. P. 56(c); 10A Charles A. Wright, Federal Practice and Procedure §2722 p.373 (3d ed. 1998) ("Because a deposition is taken under oath and the deponent's responses are relatively spontaneous, it is one of the best forms of evidence for supporting or opposing a summary-judgment motion.") In its response to the motion for summary judgment, Ferring stated that Dr. Vilhardt had never considered one way or another whether to include the omitted information, and pointed to Dr. Vilhardt's deposition testimony that he had "no idea" whether the patent office had asked for declarations from persons other than the inventors, and further that he had selected these scientists because they were "knowledgeable and connected to the field as to give a qualified opinion on the matter." See Anderson, 477 U.S. at 257 (to establish a genuine issue of material fact, the nonmoving party "need only present evidence from which a jury might return a verdict in [its] favor"). The panel majority's repeated assertions that Ferring "offered nothing" and that there was "no record evidence" to support its position are untenable, as are the credibility inferences it draws from Dr. Vilhardt's deposition testimony.[4] See

[4]My colleagues draw an adverse inference because Dr. Vilhardt initially did not recall the contacts, seventeen and thirteen years earlier,

(continued on next page)

Anderson v. Bessemer City, 470 U.S. 564, 575 (1985) (the task of weighing the credibility of witnesses is for the trier of fact); Hunt, 526 U.S. at 552 (the district court erred in granting summary judgment, in that "it either credited appellees' asserted inferences over those advanced and supported by appellants or did not give appellants the inference they were due").

At a minimum, the issue should be remanded, on correct law. It is not the law that a declarant's past affiliations are always material, and it surely is not the law that "should have known" establishes deceptive intent, which requires scienter and deliberateness. On its face, "the involved conduct, viewed in light of all the evidence," does not "indicate sufficient culpability to require a finding of intent to deceive," the standard of Kingsdown, 863 F.2d at 876. It is improper to convict this inventor of fraudulent conduct based on inference, on summary judgment. This is not law, and it is not a just procedure.

(continued from previous page)

with the scientists concerning these affidavits. After being shown file correspondence indicating such contacts, Dr. Vilhardt explained that he had not recalled these contacts, had not understood what the questioner had meant by the term "affidavit" and that, while he didn't "remember distinctly what happened in those days," he believed that most of the correspondence was handled by the attorneys.

APPENDIX B - MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

CASE NO. 02 CIV. 9851
HON. CHARLES L. BRIEANT

FERRING B.V. and
AVENTIS PHARMACEUTICALS, INC.

Plaintiffs,

-against -

BARR LABORATORIES, INC.

Defendants.

Decided: February 7, 2005

MEMORANDUM AND ORDER

Brieant, J.

Before this Court are three motions for summary judgment, filed on April 16, 2004, by Defendant Barr Laboratories, Inc. ("Barr"), seeking an Order stating that: (1) Defendant did not infringe Plaintiffs' ("Ferring") patent-in-suit (Doc. # 119); (2) claims 6 and 11 of the patent-in-suit are invalid (Doc. # 121); and (3) the patent-in-suit is unenforceable for Plaintiffs' inequitable conduct during the patent prosecution (Doc. # 123). On May 21, 2004, Plaintiffs filed a motion for summary judgment of

Defendant's infringement of their patent, but by letter dated July 1, 2004, withdrew the motion. The remaining motions were argued on July 7, 2004. The Court has received continued letter brief correspondence from the parties through January of 2005.

Facts

Familiarity of the reader with all prior proceedings is assumed. Plaintiff Ferring B.V. "Ferring") is a privately held company organized under the laws of the Netherlands. Ferring is the owner and assignee of the U.S. Patent No. 5,407,398 entitled "DDAVP Antidiuretic and Method Therefor" ("'398 patent"). The '398 patent issued on September 10, 1991. The invention disclosed and claimed in the '398 patent is an orally effective form of desmopressin ("DDAVP") designed to be absorbed by the body through the gastrointestinal tract. Desmopressin is a synthetic analog of a naturally occurring pituitary hormone. The invention is the antidiuretic compound 1-deamino-8-D-arginine vasopressin, and is useful in treating diabetes insipidus.[1]

Plaintiff Aventis Pharmaceuticals, Inc. ("Aventis") is a Delaware Corporation licensed to market and sell the invention of the '398 patent in the United States. Aventis is the holder of an approved new drug application ("NDA"), No. 019-955, for desmopressin acetate tablets which are marketed in the United States under the product name DDAVP®.

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[1]Webster's Third New International Dictionary (1993) defines "diabetes insipidus" as a disorder of the pituitary gland characterized by intense thirst and the excretion of great amounts of dilute urine.

In November 2002, Plaintiffs received notice from Defendant that it had filed an abbreviated new drug application ("ANDA") prior to the expiration of the '398 patent, seeking approval from the FDA to market its generic version of desmopressin acetate tablets.

On December 13, 2002, within 45 days of the filing of Defendant's ANDA, Plaintiffs filed this patent infringement suit, pursuant to 35 U.S.C. § 271, *et seq.*, and 21 U.S.C. § 355, seeking declaratory judgment and an injunction. Defendant answered and asserted counterclaims of patent invalidity and non-infringement.

Discussion

Fed. R. Civ. P. 56(c) provides that summary judgment shall be rendered if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." In evaluating the record to determine whether there is a genuine issue as to any material fact, "the evidence of the non-movant is to be believed and all justifiable inferences are to be drawn in his favor." *Anderson v. Liberty Lobby*, 477 U.S. 242, 255 (1986).

I. Motion for Summary Judgment based on Inequitable Conduct

Defendant argues that summary judgment for inequitable conduct by Ferring is appropriate because the inventor, Dr. Vilhardt, misled the PTO examiner by submitting declarations in support of the '398 application without revealing the conflicting interests of declarants, Drs. Czernichow, Barth and Robinson, discussed below, who were undisclosed consultants to Ferring. Ferring denies any

wrongdoing, claiming that the relationships were too remote and did not constitute material adverse interests necessitating disclosure to the PTO examiner. Plaintiffs also assert that there is insufficient evidence of intent to deceive or mislead the PTO examiner.

Prosecution History of the '398 Patent

On December 17, 1985, Ferring filed an application, for what ultimately issued as the '398 patent. The two inventors on the '398 application were Dr. Hans Vilhardt, a former research director at Ferring, and Mr. Helmer Hagstam, who was then the technical director at Ferring.[2] On May 28, 1986, Dr. Vilhardt and his attorney appeared at a preliminary interview with PTO Examiners Moyer and Stone, during which they discussed the '398 application and prior art, in particular, U.S. Patent No. 3,497,491 ("Zaoral" or " '491") and U.S. Patent No. 3,454,549 ("Boissonnas" or "'549"). The examiner's written summary of the interview states that Dr. Vilhardt and his attorney argued to the examiner "that prior art does not teach administration via stomach route and that peroral implies 'buccal' etc., and that one skilled in the art would not think otherwise." *See* Gold Decl., Ex. 1.[3] Applicants agreed to "consider amending the

[2]On May 21, 1984, Dr. Vilhardt and Mr. Hagstam assigned their rights, title and interest in the "DDAVP Antidiuretic and Method Therefor" invention to Ferring. *See* Karen Robinson Decl., Ex. E. FERB 023548.

[3]Webster's Third New International Dictionary defines "peroral" as occurring through or by way of the mouth. It defines "buccal" as 1: of an oral structure: directed toward the cheek; 2: of, relating to, or involving the cheeks; 3: of, relating to, involving, or lying within the mouth: oral. It defines "sublingual" as 1: situated or occurring under the tongue 2: of, relating to, or situated near the sublingual gland.

claims and filing declarations" and the examiner agreed to wait two weeks before giving a first action. *Id.* According to the attorney for the inventors, Examiner Moyer "suggested that applicants obtain evidence from a non-inventor" which supported Dr. Vilhardt's understanding that the term "peroral" in the Zaoral patent meant "sublingual or buccal" administration only, and not through the stomach. *See Gold Decl.*, Ex. 2 at FERB 023555.

On June 12, 1986, Ferring submitted a preliminary amendment, which added three new claims, and also submitted four declarations in support of issuing the '398 patent. Of the four declarations, Dr. Vilhardt submitted two, Dr. Czernichow submitted one and Dr. Miller submitted one. *See* Robinson Decl., Ex. E at FERB 023722-753; FERB 023755-779. Each of these declarations were submitted with CV's attached. Dr. Czernichow's and Dr. Miller's declarations asserted that one skilled in the art who read the '491 Zaoral patent line describing peroral administration in connection with DDAVP would conclude that the term "peroral" referred to sublingual and/or buccal administration of DDAVP, and not to oral administration for gastrointestinal absorption.

On November 20, 1986, the USPTO, at the request of Ferring, cancelled Claims 1 and 6. It also rejected Claims 2-5 and 7-13 as anticipated by or obvious over Zaoral. On May 20, 1987, Ferring filed a request for reconsideration, arguing that the Zaoral patent did not expressly, impliedly or inherently teach the claims of the '398 application. Ferring submitted several articles relating to the subject matter in support of its position that those skilled in the art would not find the '398 patent obvious in light of Zaoral. *See* Robinson Decl., Ex. E at FERB 023573-781.

On August 14, 1987, the USPTO again rejected the claims of the '398 application based on the prior art. Ferring appealed the PTO's decision on November 13, 1987. On September 21, 1990, the Board of Patent Appeals and Interferences affirmed the examiner's rejection of the '398 patent, concluding that the "peroral" recitation by Zaoral coupled with the knowledge of the prior art, disclosed in Vavra[4], is suggestive of and anticipated the oral administration of DDAVP for gastrointestinal absorption in humans. The 1974 Vavra study involved the administration of desmopressin to rats by stomach gavage and showed that DDAVP caused antidiuresis in rats. *See* Steinhauer Decl., Ex. 13 at 9.

On November 21, 1990, Ferring responded to this rejection by the Board of Patent Appeals by filing an "Amendment After Appeal." *See* Gold Decl., Ex. 9. Along with the amendment, Ferring filed five declarations submitted by Dr. Vilhardt, Dr. Miller[5], Dr. Czernichow, Dr. Robinson and Dr. Barth. *See* Gold Decl., Exs. 10-14.

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[4]Vavra *et al.*, "Antidiuretic Action of 1-Deamino-[8-D-Arginine]-Vasopressin in Unanesthetized Rats," The Journal of Pharmacology and Experimental Therapeutics, Vol. 188, No. 1 (1974). *See* Steinhauer Decl., Ex. 3 (U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences Decision, Appeal No. 89-0259).

[5]Dr. Myron Miller was a doctor of geriatric medicine and is not challenged on this motion. He opined that the invention was unobvious to him and would be to others skilled in the art, even after a review of the references, and that the use of "peroral" in the Zaoral patent did not indicate oral administration of DDAVP for gastrointestinal absorption by humans. *See* Gold Decl., Ex. 4.

On April 8, 1991, the USPTO issued a Notice of Allowability, allowing claims 2-5 and 7-13 of the '398 patent. *See* Gold Decl. Ex. 15. The patent issued on September 10, 1991, with no written explanation as to the reason for allowing these claims after several iterations of rejection.

Barr now claims that Ferring and Dr. Vilhardt committed inequitable conduct by presenting 'noninventor' declarations in support of the '398 patent application to the PTO without disclosing the declarants' relationships with Ferring. *See* Def.'s Memo. at 11. Specifically challenged by Barr are a declaration submitted by Dr. Czernichow in 1986, and three declarations submitted by Drs. Czernichow, Barth and Robinson in 1990, after the Board of Patent Appeals affirmed the examiner's earlier rejections. Dr. Barth's and Dr. Robinson's declarations did not include CV's. Defendant argues that Ferring misled the PTO examiners by failing to disclose to them that each of these three declarants had been a consultant to Ferring and that there were other relationships requiring disclosure as adverse or conflicting. Defendant contends, and this Court agrees, that the PTO must have relied substantially on these declarations, as there is no alternative explanation offered for the Board's final allowance of the claims after several prior rejections by the PTO.

Dr. Czernichow

Dr. Czernichow, a professor of pediatrics, provided two declarations in support of the issuance of the '398 patent. The first was dated June 4, 1986, and was in direct response to the examiner's request for non-inventor declarations regarding the meaning of "peroral." In it, he states that the Zaoral patent did not teach him, and opined

that it would not teach others skilled in this art to administer DDAVP in oral dosage form for gastrointestinal absorption by humans and that the meaning of "peroral" administration in the Zaoral patent meant that DDAVP could be administered through the mouth for sublingual or buccal absorption. *See* Gold Decl. Ex. 3.

Dr. Czernichow's second declaration was submitted in 1990, and addressed the Vavra reference by the Board of Patent Appeals. In it, he states that he specializes in endocrinology and diabetes. He states that the PTO's decision that the Vavra reference in combination with Zaoral *et al.*, suggests the use of DDAVP in oral dosage form for gastrointestinal absorption in humans is a "substantial extrapolation of the results provided in the cited references and presents a conclusion that those skilled in this art would not make." *See* Gold Decl. Ex. 12. He stated that the "testing protocols applied in Vavra are highly questionable and persons skilled in the art would be very cautious in making any prediction based on these results;" the "fundamental understanding of persons skilled in peptide chemistry was that peptides were degraded in the human gut;" and that the Vavra reference regarding rats wouldn't change this understanding as to humans. *Id.*

His CV does not mention any affiliation with Ferring, but the record reveals that Dr. Czernichow was a Ferring consultant and received research funding from Ferring from 1985 to 1986, and again from about 1988 to 1990. *See* Czernichow Dep. at 24-27. Dr. Czernichow testified that as early as 1975, he was in contact with Ferring in regard to his research using the nasal formulation of DDAVP. *See* Czernichow Dep. at 22-23.

Appendix B

Dr. Robinson

Dr. Iain Robinson, a neuroendocrinologist, filed a declaration in support of the '398 patent in November of 1990, which specifically addressed the Vavra reference by the Board of Patent Appeals after Plaintiff's appeal of the rejection. *See* Gold Decl. Ex. 13. In it, Dr. Robinson states that he "carefully considered the reference cited by the Board, Vavra, et al., ... in relation to its teachings regarding the activity of DDAVP by the subcutaneous and oral route. I must respectfully disagree with the suggestion by the Board that Vavra, in combination with the Zaoral patent ['491] suggests the administration of DDAVP orally for gastrointestinal absorption." *Id.* He further stated that the Vavra reference fails as an effective reference because no evidence is presented as to the relative stability of the two peptides in either subcutaneous tissue or gastrointestinal fluids." *Id.*

No CV was provided to the PTO examiner with this declaration. During his deposition, Dr. Robinson revealed that he was employed as a pre-clinical research director at Ferring from 1985-1986, that during his tenure as research director, Ferring sponsored Dr. Vilhardt's research on the effects of DDAVP, and that Drs. Robinson and Vilhardt were friends and in regular contact during this time. *See Robinson Dep.* at 30-31; 159-160, 167. Robinson testified that he was also a paid Ferring consultant for some months before his job as research director in 1985 and then was again a paid Ferring consultant from 1986-1989. *See Id.* at 38-39. He also testified that after he left Ferring, the company sponsored a research program in his laboratory for about three years. *See Id.* at 171.

In addition to these previously undisclosed associations with Ferring and Dr. Vilhardt, Dr. Robinson also testified that at the time of his 1990 declaration, he had no expertise in DDAVP, that he did not recall having done any research on drug delivery systems or on the absorption of peptides in the gastrointestinal tract, and that he did not understand why he was retained to provide a declaration on DDAVP. *Id.* at 94.

Dr. Barth

Dr. Barth, a Professor of Organic Chemistry and Biochemistry, also submitted a declaration in support of the patent in 1990, which specifically addressed the Vavra reference and expressed his disagreement with the Board's suggestion that "Vavra in combination with Zaoral ['491] suggests the efficacy [of] oral DDAVP in humans. [] My years of experience have persuaded me that there is no justification for transferring pharmacology data obtained from one species of laboratory animals to another or to humans." *See* Gold Decl., Ex. 14.

In deposition testimony, Dr. Barth stated that he has been employed by the Academy of Science of the Czech Republic since 1963 and that from 1984 to 1987, he worked on several projects for Ferring in return for "allowances and accommodation and costs." *See* Barth Dep. at 9. He testified that from 1988 to 2000, he worked for about one month of each year on projects in Copenhagen with or for Ferring, but did not know whether those projects were funded by Ferring. *Id.* at 14-15, 17. During the deposition, Ferring's attorney "clarified" on the record that his understanding was that under the Czech system, nothing of value went personally from Ferring to Dr. Barth, but that it went through the Czech Academy of Science, by whom Dr. Barth was then

employed. *Id.* at 9. Dr. Barth testified that he was not a Ferring consultant, nor paid as a Ferring consultant. *See Id.* at 36, 38. However, he is described as a Ferring consultant in the Ferring Privilege Logs, in reference to prosecution of the '398 patent (*See* Robinson Decl. Ex. I., entries 21,30).

Dr. Vilhardt testified that he sent Barth a partial draft declaration telling him what he should state in his affidavit. *See* Vilhardt Dep. at 359-361. Dr. Vilhardt also testified that Dr. Barth was an old friend of his. *Id.* at 367.

"The defense of inequitable conduct is entirely equitable in nature, and thus is not an issue for a jury to decide." *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1318 (Fed. Cir. 2000). "Although the premises of inequitable conduct require findings based on all the evidence, a procedure that may preclude summary determination, a motion for summary judgment may be granted when, drawing all reasonable factual inferences in favor of the non-movant, the evidence is such that the non-movant can not prevail." *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 547 (Fed. Cir. 1998).

"Inequitable conduct includes affirmative misrepresentations of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive." *PerSeptive Biosystems, Inc.*, 225 F.3d at 1318; *See also Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358 (Fed. Cir. 2003). Both intent and materiality are questions of fact that must be proved by clear and convincing evidence. *Dayco*, 329 F.3d at 1363. Summary judgment is not proper when "facts of materiality or intent are reasonably disputed." *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.3d. 1182, 1189-90 (Fed. Cir. 1993).

> As a general principle, materiality and intent are balanced -- a lesser quantum of evidence of intent is necessary when the omission or misrepresentation is highly material, and vice versa. At the same time, however, there must be some threshold showing of intent to be balanced; we will not find inequitable conduct on an evidentiary record that is completely devoid of evidence of the patentee's intent to deceive the PTO. *See Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 2002 U.S. App. LEXIS 15418, at *33 (Fed. Cir. 2002) ("Materiality does not presume intent, which is a separate and essential component of inequitable conduct.").

Amgen Inc. v. Hoechst Marion Roussel, 314 F.3d 1313, 1358 (Fed. Cir. 2003) (some citations omitted).

Materiality

The governing regulations in effect during the patent prosecution stated that "information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." 37 C.F.R. § 1 .56(a) (1991) *See* Gold Decl., Ex. 22. The regulations further provided the following:

> A duty of candor and good faith toward the Patent and Trademark Office rests on the inventor, on each attorney or agent who prepares or prosecutes the application and on every other individual who is substantively involved in the preparation or prosecution of

> the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application. All such individuals have a duty to disclose to the Office information they are aware of which is material to the examination of the application.

Id. The Manual of Patent Examining Procedure in effect at that time provided:

> Affidavits or declarations should be scrutinized closely and the facts presented weighed with care. The affiant's or declarant's interest is a factor which may be considered, but the affidavit or declaration cannot be disregarded solely for that reason.

The Manual of Patent Examining Procedure § 716(3) (5th ed. 1983-1994), (*See* Gold Decl. Ex. 21).

Declarations and affidavits submitted to the PTO examiner in support of a pending patent application are generally considered to be material. *See Refac Int'l. Ltd. v. Lotus Development Corp.*, 81 F.3d 1576, 1583 ("Affidavits are inherently material, even if only cumulative."). If affiants or declarants have an interest in the pending patent, that interest may be material as well. *See Id.* at 1581 ("It would surely have been important for the examiner, and any reasonable examiner, to know of [affiant's] association with [patent assignee]..."). However, materiality of these omissions is fact-dependent, and therefore it cannot be said, as a matter of law, that every omission regarding a previous connection with a patent applicant or assignee is material. *See Id.* at 1584-85.

Intent

As direct evidence of intent is "rarely available in instances of inequitable conduct[,]" *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997), intent is more often established "by inferences drawn from facts, with the collection of inferences permitting a confident judgment that deceit has occurred." *GFI, Inc. v. Franklin Corp. et al.*, 265 F.3d 1268, 1274 (Fed. Cir. 2001). Evidence of negligence in failing to disclose material information "can support an inference of intent only when, viewed in light of the all the evidence, including evidence of good faith, the conduct is culpable enough to require a finding of intent to deceive." *Halliburton Co. v. Schiumberger Tech. Corp.*, 925 F.2d 1435, 1442 (Fed. Cir. 1991) (citations omitted). As previously stated, summary judgment is not proper when "facts of materiality or intent are reasonably disputed." *Paragon*, 984 F.3d at 1190. However, "[w]hile intent is a factual inquiry, and the standard of proof is high, the entrance of summary judgment is not, as a consequence, automatically precluded." *Id.* at 1189. "[S]moking gun evidence is not required in order to establish an intent to deceive." *Id.* at 1190. "In looking to the record for evidence of a genuine issue respecting intent to deceive the PTO, all of the circumstances, including those indicative of good faith, must be considered," but "merely conclusory statements of completely insupportable, specious, or conflicting explanations or excuses will not suffice to raise a genuine issue of fact." *Id.*

Analysis

Ferring argues that no reasonable person could believe that the affiliations of the declarants would have been important to the examiner in considering the impartiality of

their views, and that the relationships challenged by Barr "simply do not qualify as material affiliations such that a reasonable examiner would have considered them important." *See* Pl's Memo. at 6. Ferring further argues that "Barr has failed to establish any intent to deceive the PTO, even by inference." *Id.* Ferring finally argues that there are at least substantial questions of fact as to materiality and intent, such that summary judgment should be precluded. *See Id.* The Court disagrees.

In *Paragon*, the Federal Circuit concluded that an inference of an intent to deceive the PTO was established by the submission of deceptive declarations. *See Paragon*, 984 F.2d 1182. In that case, after an interview with the PTO examiner, the applicant agreed to provide three affidavits from disinterested parties to support a non-obviousness argument. The applicant in *Paragon* submitted three affidavits by professionals in the field, which attested to the advantages of the patent over the prior art. In the affidavits, the affiants averred that they had not previously been, or would in the future be employed by the corporation which was assigned the patent rights. It was later discovered that "each of the affiants held stock in [the corporation] and that one of them or all three had been consultants for which they received remuneration." *See Paragon*, 984 F.2d at 1191. The Federal Circuit Court held that the failure to disclose these connections evidenced a sufficient intent to withhold material information from the PTO.

Inequitable conduct during patent prosecution was also addressed in *Refac*, 81 F.3d 1576. In that case, the Federal Circuit affirmed the District Court's finding of intent to deceive where one of three Rule 132 affiants failed to disclose an eight week-long period of employment at the company prosecuting the patent, which had occurred about

six months prior to his submission of an affidavit on the company's behalf. The Federal Circuit upheld the lower court's finding of inequitable conduct and concluded that it could *not* "hold as a matter of law that omission of a relevant part of one's employment history on an affidavit intended to show the adequacy of the patent specification to one skilled in the art, when such an affidavit by the inventor was earlier rejected, does *not* constitute inequitable conduct." *Refac.* 81 F.3d at 1584-85 (emphasis added). In other words, deliberate omission of a relevant part of an affiant's employment history on an affidavit in support of a patent would be inequitable conduct.[2] The Federal Circuit acknowledged in *Refac* that even a mere eight-week employment relationship with a company may constitute a "relevant" fact requiring disclosure when submitting an "affidavit intended to show the adequacy" of a patent specification. The Court held that since the examiner did not allow the claims in response to the inventors' own proffers, "the inventors were on notice that the examiner would consider it important to know of the affiants' pre-existing . . . connection with the inventors." *Id.* at 1584.

Ferring submitted these affidavits to the PTO in an attempt to overcome rejection of its application. Plaintiffs were required to provide the PTO with sufficient information for a reasonable examiner to consider and weigh the proffered declarations and the opinions contained therein within their proper context. This Court finds the disclosure inadequate. This is particularly significant considering the very cumbersome and indeed mysterious prosecution history

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[2]As held by the Federal Circuit Court, "[w]e need not quibble about whether a consultant' is or is not 'employed' by a company." *Paragon*, 984 F.2d at 1192 (Fed. Cir. 1993).

of this patent, and that several iterations of renewed attempts followed several rejections of the claims before the PTO finally allowed the patent to issue. Even if the conflicted individuals in this case *were* perfectly capable of objectivity and provided declarations accordingly, it is beyond dispute that the PTO should have nonetheless been informed of the connections and prior relationships between these experts and Ferring.

The Court finds unavailing Ferring's argument that *Paragon* is inapposite because the examiner in that case specifically required that affidavits be submitted by "disinterested parties" as opposed to non-inventors, as in the case at bar. It should have been, and the Court concludes on all the evidence presented, that it must have been clear to Dr. Vilhardt at the preliminary meeting with the examiner that a non-inventor affidavit was sought for purposes of obtaining objective evidence that the invention was not anticipated by the prior art or obvious. Later, after affirmance of the examiner's rejection by the Board of Patent Appeals, it should have been all the more clear that objective opinion evidence of the unobvious nature of this invention was required.

"If a bare declaration of lack of intent to mislead where a material affidavit is submitted to the PTO were to raise a genuine issue, summary judgment would be precluded in all cases except where no response at all is made." *Paragaon*, 984 F.2d at 1191. The Court considers it relevant that Drs. Robinson and Czernichow had substantial consulting and employment relationships with Ferring. The evidence as to Dr. Barth is also troubling. In the interests of candor, his affiliations with Ferring and friendship with Vilhardt also should have been disclosed to the examiner. The effect of the fraudulent omissions from the Czernichow

and Robinson declarations is magnified by the lack of candor in the Barth affidavit.

On the totality of the facts in this case, this Court finds an intent to deceive where Defendants failed to disclose that both Drs. Robinson and Czernichow and probably Barth were consultants to Ferring for significant periods and that Dr. Robinson was an actual employee of Ferring. Ferring's funding of Dr. Czernichow's research on DDAVP from 1985 to 1986 was just prior to, or contemporaneous with, Czernichow's first declaration for Ferring submitted in 1986. At the time of his second declaration in 1990, Dr. Czernichow had again been very recently or contemporaneously receiving funding from Ferring. Yet, Dr. Czernichow's CV made no mention of his then current or very recent relationships maintained with Ferring. *See* Gold Decl., Ex. 23. This is so, despite the very clear understanding of Ferring that the PTO was interested in receiving non-inventor testimony, which, again, had to have indicated that an objective perspective was sought. The Court is left to wonder why such an obvious problematic interest would not be revealed at the outset, so as to avoid any cause for suspicion. The purpose of such disclosure is to ensure that the examiner has all material information on which to make a judgment. Heeding this duty of candor may have prevented the veil of suspicion and mystery that now surrounds this prosecution history.

> Typically, a finding of inequitable conduct hinges on whether the evidence as a whole indicates that patentees or their representatives acted with the intent to deceive. When balanced against high materiality, the showing of intent can be proportionally less.

Brasseler, v. Stryker Sales Corp., 267 F.3d 1370, 1380-81 (Fed. Cir. 2001) (citations omitted).

The undisputed evidence in this case supports the finding of inequitable conduct by the patentee and its agents and the grant of summary judgment. The reluctance of the PTO to issue the '398 patent was evident. Each affidavit submitted in support of its issuance was thus highly material to the prosecution history. That three of the challenged declarations were submitted after several iterations of rejected attempts to obtain the patent's issuance speaks loudly as to motive and intent. While credibility determinations from a courtroom observation may at times be necessary on the issue of intent, here, the entire record presents clear and convincing evidence of an intent to mislead the examiners, even viewing the evidence, as it must be viewed, in the light most favorable to Plaintiff. The submission of the Czernichow and Robinson declarations, and to a lesser extent that of Barth, support a finding of intent to mislead the PTO. "The inference [of an intent to mislead] arises not simply from the materiality of the affidavits, but from the affirmative acts of submitting them, their misleading character, and the inability of the examiner to investigate the facts." *Paragon*, 984 F.2d at 1191.

Because "the habit of charging inequitable conduct in almost every major patent case has become an absolute plague," *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988), where, as in this case, the Court finds that the initial threshold for materiality and intent have been met by clear and convincing evidence, it must then go on to determine "whether the applicant's conduct is *so culpable* that the patent should be held unenforceable." *Dayco Prods., Inc. v. Total Containment, Inc.* 329 F.3d 1358, 1363 (Fed. Cir. 2003) (emphasis in original). It is. The

deceit was practiced over a long period of time by more than one person and appears to have been outcome determinative. As earlier discussed, the close and undisclosed long-standing associations between the declarants in this case and Ferring and Vilhardt should have been disclosed in order to avoid the foreseeable inference of fraud that logically arises from the undisputed facts of this case. *See Molins PLC v. Textron*, 48 F.3d 1172, 1182 (Fed. Cir. 1995) ("Those who are not 'up front' with the PTO run the risk that, years later, a fact-finder might conclude that they intended to deceive.").

The totality of the circumstances in this case reveal that no genuine issues of material fact as to inequitable conduct remain so as to preclude summary judgment. The Court therefore finds the patent unenforceable on that ground. For the reasons set forth, the motion for summary judgment based on inequitable conduct is granted in favor of Defendant.

II. Motion for Summary Judgment based on Non-Infringement

Defendant's position as to non-infringement is less clear than the evidence supporting this Court's determination that Ferring's '398 patent is unenforceable due to inequitable conduct. In the interest of a complete record and to limit the transactional costs imposed on the parties by this litigation, the Court will now consider this alternate basis for summary judgment.

Ferring alleged that Barr's ANDA no. 76-470 infringes claims 1-3, 5-9, and 11 of the '398 patent. Barr asserts that the tablets described in its ANDA do not infringe any claims in the '398 patent because: 1) Barr's product contains desmopressin acetate, rather than 1-deamino-8-D-

arginine vasopressin as claimed in the patent; 2) the tablets do not contain a composition or an amount of 1-deamino-8-D-arginine vasopressin that is for "absorption in the gastrointestinal tract"; 3) the tablets do not contain amounts of 1-deamino-8-D-arginine vasopressin within the specified dosages in claims 4, 5, 7 and 8; and 4) the tablets do not have any "gastrointestinally *adsorbable*" as opposed to *absorbable* amount of 1-deamino-8-D-arginine vasopressin as claimed in claims 6-9.[3] Barr also contends that Ferring did not pursue infringement on a doctrine of equivalents theory prior to this summary judgment motion, and thus is barred from asserting this theory now.[4]

"An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. ... The second step is comparing the properly construed claims to the device accused of infringing." *Markman v. Westview Instruments, Inc.*, 52 F. 3d 967, 976 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996). A patent is infringed only where the patentee shows that an allowed claim in the patent is found either literally or by equivalents in the accused device.

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[3]Since the lawsuit was filed, a Certificate of Correction has been granted to Ferring by the PTO for Claim 6. The certificate changes the "d" in "adsorbable" to a "b" for "absorbable." Clearly this was a simple typographical or scrivener error of the sort upon which substantial rights should not depend.

[4]Plaintiff's Opening Claim Construction Brief asserts that Plaintiff reserves the right to argue that Barr infringes the asserted claims under the doctrine of equivalents, should the Court construe some of the claim terms differently than Plaintiff's proposed interpretation.

> Upon construction of the claims, summary judgment may follow when it is shown that the infringement issue can be reasonably decided only in favor of the movant, when all reasonable factual inferences are drawn in favor of the non-movant. Such judgments usually turn on the claim construction.

Voice Techs. Group, Inc. v. VMC Sys., Inc. 164 F.3d 605, 612 (Fed. Cir. 1999).

To prevail on non-infringement, Barr need only show that "one limitation of each asserted claim is not met" in its accused ANDA product. *Techsearch LLC v. Intel Corp.*, 286 F.3d 1360, 1381 (Fed. Cir. 2002); *see also Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1535 (Fed. Cir. 1991) ("The failure to meet a single limitation is sufficient to negate infringement of the claim..."). The Court is persuaded that Barr's ANDA does not infringe the '398 patent because the patent discloses the claim term "l-deamino-8-D-arginine vasopressin," which was not satisfied either literally or by equivalents in Barr's ANDA, which contains "desmopressin acetate." Because the construction of this disputed term should be dispositive, the Court will limit its analysis accordingly.

Claim Construction

"To ascertain the meaning of claims, we consider three sources: The claims, the specification, and the prosecution history." *Markman*, 52 F.3d at 979 (Fed. Cir. 1995) (citations omitted). "The court may, in its discretion, receive extrinsic evidence in order to aid the court in coming to a correct conclusion as to the true meaning of the language employed in the patent." *Id.* at 980 (quotations omitted).

"Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Id.*

The "claim construction inquiry ... begins and ends in all cases with the actual words of the claim." *Renishaw PLC v. Marposs Societa per Anzioni,* 158 F.3d 1243, 1248 (Fed. Cir. 1998). There is a "heavy presumption" that the terms used in the claims "mean what they say, and have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art." *Texas Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202 (Fed. Cir. 2002). Claims are to be construed from the perspective of one skilled in the field of the patent. *Brookhill-Wilk I, LLC. v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298 (Fed. Cir. 2003).

At the time of this patent prosecution, the antidiuretic qualities of desmopressin were already well known, but the means of administration (usually intranasally by use of a rhinyle) were considered awkward or undesirable. It had "been traditionally accepted that proteins and peptides, such as DDAVP, are decomposed in the stomach and intestines without substantial, or any absorption taking place." '398 Patent. The stated objects of the '398 patent invention included "to avoid or substantially alleviate the ... problems of the prior art" and "to provide DDAVP compositions which dissolve in the gastrointestinal tract in order to allow for the gastrointestinal absorption of DDAVP." *Id.* The invention of the '398 patent was to achieve an antidiuretic effect in a diabetic patient merely by swallowing a pill containing DDAVP for gastrointestinal absorption. The DDAVP disclosed in the patent is *1-deamino-8-D-arginine vasopressin.*

Claims 1-5 cover the patented compositions and claims 6-11 cover specific methods of administration. The dispositive term "l-deamino-8-D-arginine vasopressin" is first recited in Claim one, which discloses:

> An antidiuretic composition for humans comprising a gastrointestinally absorbable, antidiuretically effective, amount of l-deamino-8-D-arginine vasopressin and a pharmaceutically acceptable carrier in solid oral dosage form for absorption in the gastrointestinal tract of said humans.

'398 Patent, col. 4, 11. 24-29. Defendant contends, and this Court agrees, that the term "1-deamino-8-D-arginine vasopressin" ("DDAVP" or "desmopressin") means exactly that, and the claims must be construed to instruct one practicing the art of the patent to use the active compound (or free base) desmopressin, and not as extending to its salts.

The Merck Index defines "desmopressin" as an "analog of vasopressin possessing high antidiuretic activity" and provides "l-desamino-8-D-arginine vasopressin"[5] as a construct of "desmopressin." *The Merck Index* 10th Ed. (1983) at 422. *See* Karen Robinson Decl., Ex. P.

Plaintiffs assert that Defendant's desmopressin acetate product infringes the patent because the term "1-deamino-8-D-arginine vasopressin" would be understood by one of ordinary skill in the art as "the active compound

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[5]"Desamino" is deemed a variation of the word "deamino." *See* Webster's Third New International Dictionary defining "desamination" as a different spelling of "deamination."

desmopressin and any of its salts." *See* Pl.'s Memo. at 12. Plaintiffs admit that in their own products, as presently made and sold, they do not practice their own invention covered by the '398 patent. *See* Hearing Tr. at 31. They in fact also use desmopressin acetate," a different chemical compound and exactly what Defendant seeks to use in its ANDA. The claims of the patent cannot be construed in light of the accused product nor in light of Plaintiff's own currently marketed products. They must be construed in light of the public record.

At the outset, the Court considers recent Federal Circuit cases, which have addressed related issues. In *Merck & Co. v. Teva Pharmaceuticals USA, Inc.*, 347 F.3d 1367 (Fed. Cir. 2003), the Court concluded that a sodium salt form of a claimed acid used to treat osteoporosis and Paget's disease literally infringed a patent although the sodium salt form was not explicitly specified in the claim itself. The patent claims specifically used the term "acid" in disclosing the method of treatment. In holding that the patent should be read to extend to the acid's salt forms, the Circuit Court relied on the following three factors: 1) the specification contained numerous references to the salt forms of the claimed acid in describing its application; 2) the testimony from all qualified witnesses indicated that persons skilled in the field would understand that the acid was administered in the form of the salt; and 3) extensive evidence that the persons in the field used the same lexicography as the inventors by referring to the active ingredient in the form of a salt. *See Id.* at 1370-71.

Merck is readily distinguished from the case at bar in that Ferring's '398 patent specification does not define DDAVP or "1-deamino-8-D-arginine vasopressin" to include the salt form. Nor did the inventors disclose numerous (or

any) usages of salt forms in the patent specification. The Circuit Court in *Merck* placed substantial reliance on the specification's numerous references" to the salt form of the claimed acid in reaching its conclusion that salt forms were covered by the patent. The '398 patent specification provides no comparable basis for imputing the salt forms of DDAVP into the '398 patent. Nor does all of the expert testimony in this case convincingly indicate that a person skilled in the field would understand "1-deamino-8-D-arginine vasopressin" to be the same as any of its salts.

Plaintiffs expert, Dr. Verbalis, an endocrinologist, stated in his expert report that the "composition claimed in claim 1 is a solid oral dosage form comprising the active ingredient desmopressin acetate." *See* Steinhauer Decl., Ex. 4 at 8. He also testified that anyone in his "field at the time would...understand that it had to mean desmopressin acetate because if you look further down in Column 1...not only did they define DDAVP, or 1-deamino-8-D-arginine vasopressin, as the product of the Zaoral patent, they further described it in terms of its current use, at the time that this patent was filed." *See* Steinhauer Decl., Ex. 2 at 217. When asked if he reads 1-deamino-8-D-arginine vasopressin to refer to desmopressin acetate and not desmopressin in its free base, he responded: "When I read the name of a peptide like that, I allow that it could be any of the salts that are commonly used to manufacture those peptides." *Id.* at 21.

A second expert for Plaintiffs, Dr. Coy, when asked if there is a difference between the salt form and the free base form used in a compound, conceded that there is "a difference in the formulation, because one is - contains a counterion and one does not contain a counterion...this may affect things like solubility and physical chemical properties, basically nothing else." *See* Gioconda Decl., Ex. N at 389.

He also stated that "[o]nce they're injected they're identical,"(*see Id.*), but admitted that his own peptide patents recite "the pharmaceutically acceptable salts" to ensure that the salts are covered by the claims of his patents. *See Id.* at 367, 398.

A third expert for Plaintiffs, Lewis Kinter, Ph.D., a medical physiologist, stated in his expert report: "Whether salt or free base, it makes no difference at all with respect to the pharmacological activities of a drug, once in a solution." *See* Steinhauer Decl., Ex. 5 at 18. He also stated that the "terms '1-deamino-8-D-arginine vasopressin,' DDAVP, or desmopressin would be construed by a pharmacologist, physician or other scientist of ordinary skill involved with DDAVP to include all of the salt forms mentioned[.]" *See Id.*

Defendant's expert, Dr. Amidon, a professor of pharmacy, stated the following in an expert report:

> The claim term "1-deamino-8-D-arginine vasopresin" is a relatively simple chemical name for desmopressin of known chemical formula $C_{46}H_{64}N_{14}O_{12}S_2$. The salt desmopressin acetate designates a different chemical formula ($C_{48}H_{68}N_{14}O_{14}S_2$), consistent with the fact that it is a different compound. By using the chemical formula in defining the claimed invention, the '398 patent leaves no ambiguity that it is referring to desmopressin specifically, rather than to any of the other possible modified chemical compounds that can be prepared from the specific desmopressin compound. *Because a person formulating drug products would assume the drafters of the claim meant to use*

> *the term "1-deamino-8-D-arginine vasopressin" in a scientifically accurate manner, I do not believe that the claims cover a composition using desmopressin acetate instead of desmopressin.*

See Steinhauer Decl., Ex. 12 (emphasis added). This Court agrees. Dr. Amidon correctly notes that despite Dr. Vebalis' averment that the '398 patent describes administering desmopressin acetate, the patent in fact "never mentions desmopressin acetate." *Id.* He also notes that this admission is significant because the difference between desmopressin and desmopressin acetate is highly significant to a person investigating potential formulations for oral delivery." *Id.*

Incredibly, Dr. Verbalis' expert report defines Claim one of the patent as describing "the active ingredient *desmopressin acetate*," without even a tip of the hat to the fact that no salt is actually named in the claim. *See* Steinhauer Decl., Ex. 4 at 8 (emphasis added). Indeed, on the next page of his report, he contradicted that definition, stating: "the active ingredient, in this case, *desmopressin*, is gastointestinally absorbable..." *Id.* at 9 (emphasis added). Dr. Coy's testimony confirmed that the chemical formulas for the free base and salt forms were distinct, and from his testimony, it can be inferred that it is proper patent practice to claim the salt forms of a patented peptide. The Court is not persuaded by Plaintiffs' expert testimony, that the patent should be extended to cover salt forms of desmopressin.

In *Stephens et al. v. Tech International., Inc.*, 2004 U.S. App. LEXIS 27064 (December 29, 2004), the Federal Circuit recently considered whether an accused salt form of a

patented product was covered by the patent, in the context of determining whether an infringement suit was frivolous.[6] The patent disclosed a means of removing unwanted substances from human urine samples. After conducting an infringement analysis, the Court held that the plaintiff had adequate grounds to believe that there was direct infringement, and that the suit was therefore not frivolous. The Court held:

> While the '647 patent does not use the word "salt," the compelling evidence in this case that persons of skill in the field of urinalysis know of chromic acid and sodium dichromate's interchangeable use for removal of unwanted substances in urine samples outweighs that fact.

Stephens, 2004 U.S. App. LEXIS 27064, at *13. The Court then held: "Because the use of chromic acid encompasses the use of sodium dichromate in the field of urinalysis, Spectrum had adequate grounds to believe that Tech directly infringed the '647 patent." *Id.* Importantly, the Circuit Court limited the scope of its holding by declaring: "We do not announce that all claims of an acid inherently claim the acid's salt form; it must still be determined whether or not persons having skill in the applicable art deem the acid and salt to be interchangeable." *Id* at *13.

The Court does not interpret the *Stephens* decision to materially alter the standards of claim construction and

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[6]Plaintiffs appealed the District Court's grant of attorney's fees to defendant after finding the case to be exceptional, based in part on its finding that the infringement suit was frivolous.

infringement analysis when the accused product is a salt form of a claimed compound. The *Stephens* decision is silent as to the weight that should be given to the presence or absence in a patent specification of references to salt forms, and should not be read as limiting or disapproving the rule in *Merck*.

Despite the lack of any reference to salts in the specification in this case, Plaintiffs argue that the specification's reference to the Zaoral patent ('491), which does include salt forms, indicates that their invention should also be construed as to include salt forms of the active ingredient. The Court disagrees. The '398 patent specification defines "1-deamino-8-D-arginine vasopressin" as "DDAVP" and states: "this invention relates to the antidiuretic compound 1-deamino-8-D-arginine vasopressin, which is commonly known as DDAVP. DDAVP exhibits a high and specific antidiuretic activity and is useful in treating diabetes insipidus as disclosed in U.S. Pat. No. 3,497,491 [Zaoral]." *See* U.S. Pat. No. '398. "Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference..." *See* Manual of Patent Examining Procedure § 608.01(p), Ex. G. It does not follow that Plaintiffs or the Court can enlarge the right to exclude others by the reference to the '491 patent. The Federal Circuit in *Markman* instructed that the "written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims." *Markman*, 25 F.3d at 979-980. "When a patent drafter discloses but declines to claim subject matter ... this action dedicates that unclaimed subject matter to the public." *Johnson & Johnston Assocs. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002). Ferring had the opportunity to

claim the salt forms and in failing to do so, failed to cover Barr's desmopressin acetate product.

Plaintiffs also argue that "l-deamino-8-D-arginine vasopressin" should include salts under *Pfizer v. Dr. Reddy's Laboratories*, 359 F.3d 1361 (Fed. Cir. 2004) and Federal Food and Drug Administration ("FDA") definitions. That case is readily distinguished on its facts. In it, Pfizer owned a patent which covered the administration of the drug amlodipine in both its besylate and maleate salt forms. Pfizer obtained an extension of that patent under the Patent Term Restoration Act of 1984 (codified at 35 U.S.C. § 156), but in its application had identified the drug in only the besylate salt form. The Federal Circuit held that the patent term extension applied to the drug's active ingredient, amlodipine and to its salts and esters. The Court looked to the codification of the patent extension, which specifically defined a "drug product" for purposes of the extension to mean to include "the active ingredient ... and any salt or ester of the active ingredient." *See* 35 U.S.C. §156(f)(l)(A); (f)(2).

The Federal Circuit also considered 21 C.F.R.§ 60.3(b)(10), which is specifically referenced in 35 U.S.C. §156, and defines a "human drug product" to be "the active ingredient of a new drug or human biologic product (as those terms are used in the Act and the Public Health Service Act), including any salt or ester of the active ingredient." *See* 21 C.F.R. § 60.3(b)(l0). "Pharmaceutical equivalents" is defined to be "drug products in identical dosage forms that contain identical amounts of the identical active drug ingredient, i.e., the same salt or ester of the same therapeutic moiety..." *See* 21 C.F.R. § 320.1(c). In *Pfizer*, the Federal Circuit specifically construed and applied the patent term extension statute, which is not the task before this Court.

Similarly, the FDA definitions cited by Plaintiffs relate to patent term extensions and bioequivalence for purposes of new drug approval processes, which are not implicated in this analysis. Neither *Pfizer* nor the FDA definitions appreciably alter the Court's task of claim construction in this case, nor do they relieve Ferring of the traditional obligation to specify accurately the invention claimed.

Finally, Plaintiffs refer to the Physicians' Desk Reference, which lists pharmaceuticals and discloses their contents for physicians. "DDAVP®" is a trade name for Ferring's intranasal and injection products, each of which contains desmopressin acetate. *See* Tr. at 12. Accordingly, the desk reference indicates that Ferring's DDAVP® products contain desmopressin acetate. *See* Steinhauer Decl., Ex. 8. This reference book, which defines accurately Plaintiffs' products as sold on the market, which undisputedly contain desmopressin acetate, does not define, amend or amplify the claims in Plaintiffs' '398 patent.

Barr submitted a supplemental memorandum on June 9, 2004, arguing that Ferring contradicted its infringement argument in this case by submission of a "Citizen Petition" to the FDA for consideration by that body in connection with Barr's ANDA application. In the petition submitted on or around February 2, 2004, Ferring requested that the FDA establish unique evidentiary requirements of bioequivalence limited to ANDAs of oral products containing desmopressin. Ferring argued that as the first and only approved oral peptide, it presents "complex and novel bioavailability issues." *See* Donovan Decl., Ex. A. It argued that because the product is "primarily indicated for use in children, enhancing the requirements is especially appropriate." *See Id.* Barr now argues that Ferring's Citizen Petition is a factual admission that Barr's ANDA tablet is not bioequivalent, as

Ferring asserts in this litigation. Ferring denies any contradiction between Ferring's arguments in this litigation and in the Citizen Petition.

Ferring requested in its Citizen Petition that the FDA require ANDAs for products containing desmopressin to address the unusual properties of desmopressin (including a very low absorption rate and high potency). Ferring asked the FDA to require such ANDAs to include more stringent evidentiary proofs, including comparative clinical studies as to variability of absorption and duration of action, and separate evidence of bioequivalence for each dose level.

The Citizen Petition does appear to this Court to invoke the traditional estoppel against taking inconsistent positions in companion proceedings, and suggests by implication that the testing proffered in support of the initial NDA filed by Aventis and approved by the FDA in 1995[7] is now considered inadequate. On the other hand, the filing of such a Citizen Petition may be nothing more than a hardball litigation tactic, motivated by a desire to keep out competition for as long as possible after the expiration of the patent and raise the transactional costs for Barr. Such antics are privileged under the First Amendment right to petition and are part of the rough and tumble which characterizes the free market. The Citizen Petition casts serious doubt on the genuineness of Ferring's insistent contention that Barr's ANDA is bioequivalent and its product would infringe. On balance, the Court is constrained to determine that the Citizen Petition does not rise to the level of an admission of fact precluding Ferring's claims of infringement.

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[7] *See* U.S. FDA Center for Drug Evaluation and Research, www.accessdata.fda.gov.

Doctrine of Equivalents[8]

In Plaintiffs' amended opposition memorandum, they argue that even if the Court construes the claims of the patent as suggested by Barr, there is still infringement under the Doctrine of Equivalents. Plaintiffs argue that even if differences exist between desmopressin and its acetate form before being swallowed, once either reaches the gastrointestinal tract, it is the same desmopressin. *See* Pl. Opp. at 18. Defendant responds that this doesn't matter because the patent doesn't address the invention's interaction with gastric fluids or breakdown in the gastrointestinal tract before absorption.

> A device that does not literally infringe a claim may nonetheless infringe under the doctrine of equivalents if every element in the claim is literally or equivalently present in the accused device. A claim element is equivalently present in an accused device if only "insubstantial differences" distinguish the missing claim element from the corresponding aspects of the accused device.

Sage Prods. v. Devon Indus., 126 F.3d 1420, 1423-1424 (Fed. Cir. 1997)(citations omitted).

Plaintiffs themselves now produce and sell desmopressin acetate, the same product that Defendant proposes to sell, and that they charge as infringing. Tellingly, Plaintiffs concede that their product is not the

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[8]The Court assumes without deciding the Plaintiffs properly preserved and presented this argument.

same as that described in the patent, which the Defendant allegedly infringes. *See* Hearing Transcript at 31 (The Court: "[H]e tells me that neither side of the case practices the patent. Everybody sells desmopressin acetate." Mr. Mondolino (attorney for Plaintiffs): "Well, we agree. We don't practice our own invention."). In the face of such an admission, the Court could not in logic conclude that Defendant infringes a patent, even by equivalents, by producing the same product as Plaintiffs who don't practice their own invention. "The doctrine of equivalents cannot be used to erase meaningful structural and functional limitations of the claim on which the public is entitled to rely in avoiding infringement." *Conopco, Inc. v. May Dep't Stores Co.*, 46 F.3d 1556, 1562 (Fed. Cir. 1994) (citations omitted). The Court does not find the change in formula to be an insubstantial change when Plaintiffs themselves admit that the acetate product is not their patented invention. Here, Plaintiffs failed to claim the salt forms of DDAVP and the Court is constrained by the "fundamental principle that claims define the scope of patent prosecution." *Id.* at 1052. Plaintiffs cannot now expand their patent through the doctrine of equivalents.

There is no genuine dispute that the term "1-deamino-8-D-arginine vasopressin" does not literally define or include an acetate or other salt form of desmopressin. Had the inventors intended to claim desmopressin acetate, they could have said so. It cannot be said with any certainty that an ordinary person skilled in the art would *know* that reference in the patent to "1-deamino-8-D-arginine vasopressin" is an instruction to use the acetate form. "[A]s between the patentee who had a clear opportunity to negotiate broader claims but did not do so, and the public at large, it is the patentee who must bear the cost of its failure to seek protection for this foreseeable alteration of its

claimed structure." *Sage Prods. v. Devon Indus.*, 126 F.3d 1420, 1425 (Fed. Cir. 1997).

The Court concludes that Defendant's desmopressin acetate product does not literally or by equivalents infringe Plaintiffs' patent and accordingly grants summary judgment on that alternate basis. In light of this conclusion, the Court does not reach Defendant's motion for partial summary judgment for invalidity of Claims 6 and 11.

Conclusion

For the reasons set forth above, the Court grants summary judgment in favor of Defendant on the bases of inequitable conduct and non-infringement. Defendant's motion for partial summary judgment of invalidity of Claims 6 and 11 is denied.

Counsel shall settle a final declaratory judgment on five (5) days notice.

SO ORDERED.

Dated: White Plains, New York
February 7, 2005

Charles L. Brieant
United States District
Judge

APPENDIX C — ORIGINAL ORDER BY THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DENYING THE PETITION FOR PANEL REHEARING AND REHEARING EN BANC

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

05-1284

FERRING BV., Plaintiff-Appellant, and AVENTIS PHARMACEUTICALS, INC., Plaintiff-Appellant, v. BARR LABORATORIES, INC., Defendant-Appellee.

2006 U.S. App. LEXIS 10765

April 10, 2006, Decided
April 10, 2006, Filed

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the Appellant,* and a response thereto having been invited by the court and filed by the Appellee, and the petition for rehearing and response, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and

---

* This petition was filed by Ferring B.V.

the same hereby is, DENIED.

The mandate of the court will issue on April 17, 2006.

APPENDIX D — REVISED ORDER BY THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DENYING THE PETITION FOR PANEL REHEARING AND REHEARING EN BANC

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2005-1284

FERRING B.V., Plaintiff-Appellant, and AVENTIS PHARMACEUTICALS, INC., Plaintiff-Appellant, v. BARR LABORATORIES, INC., Defendant-Appellee.

2006 U.S. App. LEXIS 10811

April 12, 2006, Decided
April 12, 2006, Filed

Before MICHEL, Chief Judge, NEWMAN, MAYER, LOURIE, RADER, SCHALL, BRYSON, GAJARSA, LINN, DYK, and PROST, Circuit Judges.

ORDER

A combined petition for panel rehearing and rehearing en banc was filed by Ferring B.V.[1], and a response thereto was invited by the court and filed by Barr Laboratories, Inc. The petition for rehearing was referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc, response and the amicus curiae brief were referred to the circuit judges who are authorized to request a poll whether to rehear the appeal en banc. A poll was requested, taken, and failed.

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[1]The Pharmaceutical Research and Manufacturers of America filed an amicus curiae brief.

Upon consideration thereof,

IT IS ORDERED THAT:

(1) The petition for panel rehearing is denied.

(2) The petition for rehearing en banc is denied.

(3) The mandate of the court will issue April 19, 2006.

NEWMAN, LOURIE, and GAJARSA, Circuit Judges, would rehear the appeal en banc.

APPENDIX E —37 C.F.R. § 1.56 (1990)

§ 1.56 Duty of disclosure; fraud; striking or rejection of applications.

(a) A duty of candor and good faith toward the Patent and Trademark Office rests on the inventor, on each attorney or agent who prepares or prosecutes the application and on every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application. All such individuals have a duty to disclose to the Office information they are aware of which is material to the examination of the application. Such information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. The duty is commensurate with the degree of involvement in the preparation or prosecution of the application.

(b) Disclosures pursuant to this section must be accompanied by a copy of each foreign patent document, non-patent publication, or other non-patent item of information in written form which is being disclosed or by a statement that the copy is not in the possession of the person making the disclosure and may be made to the Office through an attorney or agent having responsibility for the preparation or prosecution of the application or through an inventor who is acting in his or her own behalf. Disclosure to such an attorney, agent or inventor shall satisfy the duty, with respect to the information disclosed, of any other individual. Such an attorney, agent or inventor has no duty to transmit information which is not material to the examination of the application.

(c) Any application may be stricken from the files if:

Appendix E

(1) An oath or declaration pursuant to § 1.63 is signed in blank;

(2) An oath or declaration pursuant to § 1.63 is signed without review therof by the person making the oath or declaration;

(3) An oath or declaration pursuant to § 1.63 is signed without review of the specification, including the claims, as required by § 1.63(b); or

(4) The application papers filed in the Office are altered after the signing of an oath or declaration pursuant to § 1.63 referring to those application papers.

(d) No patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or gross negligence. The claims in an application shall be rejected if upon examination pursuant to 35 U.S.C. 131 and 132, it is established by clear and convincing evidence (1) that any fraud was practiced or attempted on the Office in connection with the application, or in connection with any previous application upon which the application relies, or (2) that there was any violation of the duty of disclosure through bad faith or gross negligence in connection with the application, or in connection with any previous application upon which the application relies.

(e) The examination of an application for compliance with paragraph (d) of this section will normally be delayed until such time as:

(1) All other matters are resolved, or

(2) Appellant's reply brief pursuant to § 1.93(b) has been received and the application is otherwise prepared for consideration by the Board of Patent appeals and Interferences, at which time the appeal will be suspended for examination pursuant to paragraph (d) of this section.

The prosecution of the application will be reopened to the extent necessary to conduct the examination pursuant to paragraph (d) of this section including any appeal pursuant to § 1.191. If an appeal has already been filed based on a rejection on other grounds, any further rejection under this section shall be treated in accordance with § 1.93(e).

(f) Any member of the public may seek to have an application stricken from the files pursuant to paragraph (c) of this section by filing a timely petition to strike the application from the files. Any such timely petition and any accompanying papers will be entered in the application file if the petition and accompanying papers (1) specifically identify the application to which the petition is directed, and (2) are either served upon the applicant in accordance with § 1.248, or filed with the Office in duplicate in the event service is not possible. Any such petition filed by an attorney or agent must be in compliance with § 10.18.

(g) A petition to strike an application from the files submitted in accordance with the second sentence of paragraph (f) of this section will be considered by the Office. An acknowledgement of the entry of such a petition in a reissue application file will be sent to the member of the public filing the petition. A member of the public filing such a petition in an application for an original patent will not receive any communications from the Office relating to the petition, other than the return of a self-addressed postcard

which the member of the public may include with the petition in order to receive an acknowledgement by the Office that the petition has been received. The Office will communicate with the applicant regarding any such petition entered in the application file and may require the applicant to respond to the Office on matters raised by the petition. The active participation of the member of the public filing a petition pursuant to paragraph (f) of this section ends with the filing of the petition and no further submission on behalf of the petitioner will be acknowledged or considered unless such submission raises new issues which could not have been earlier presented, and thereby constitutes a new petition.

(h) Any member of the public may seek to have the claims in an application rejected pursuant to paragraph (d) of this section by filing a timely protest in accordance with § 1.291. Any such protest filed by an attorney or agent must be in compliance with § 10.18.

(i) The Office may require applicant to supply information pursuant to paragraph (a) of this section in order for the Office to decide any issues relating to paragraphs (c) and (d) of this section which are raised by a petition or a protest, or are otherwise discovered by the Office.

(j) If any disclosure pursuant to this section does not include a copy of each foreign patent document, non-patent publication, or other non-patent item of information in written form which is being disclosed or a statement that a copy thereof is not in the possession of the person making the disclosure, applicant will be so notified and given a period of time within which to file the copy or a statement that a copy is not in the possession of the person making the

disclosure. The time period set may be extended under § 1.136.

APPENDIX F — 37 C.F.R. § 1.56 (2006)

§ 1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

Appendix F

(1) prior art cited in search reports of a foreign patent office in a counterpart application, and

(2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application;

(2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

(e) In any continuation-in-part application, the duty under this section includes the duty to disclose to the Office all information known to the person to be material to patentability, as defined in paragraph (b) of this section, which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

(2)

No. 06-372

Supreme Court, U.S.
FILED
SEP 22 2006
OFFICE OF THE CLERK

IN THE
Supreme Court of the United States

FERRING B.V. AND AVENTIS PHARMACEUTICALS, INC.,

Petitioners,

v.

BARR LABORATORIES, INC.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF IN OPPOSITION

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, Respondent Barr Laboratories, Inc. states that it is a wholly owned subsidiary of Barr Pharmaceuticals, Inc., which is a publicly held company.

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INTRODUCTION

The petition for certiorari in this case is wholly contrived: it presents questions that were never raised below, conjures up contrived "circuit splits," and assails the Federal Circuit's treatment of regulations that have been subsequently amended. Tellingly, petitioners have little to say about *this case*, instead launching for the first time a broadside on the doctrine of inequitable conduct itself. These arguments are waived and, thus, the petition should be denied.

As petitioners all but concede, the Federal Circuit broke no new legal ground in this case, but merely applied its own settled precedent to the unique facts presented. Both the "'determination of whether withheld information meets a threshold level of materiality and intent to mislead,'" and the "'weighing of materiality and intent in light of all of the circumstances to determine whether the applicant's conduct is *so culpable* that the patent should be held unenforceable,'" are quintessentially fact-specific exercises trusted to the sound discretion of the district court. *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1362-63 (Fed. Cir. 2003) (quoting *Purdue Pharma L.P. v. Boehringer Ingelheim GMBH*, 237 F.3d 1359, 1366 (Fed Cir. 2001) (in turn citing *Baxter Int'l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1327 (Fed. Cir. 1998))) (emphasis in original). Now, having lost in the district court, lost on appeal, and failed to obtain a single dissent from denial of rehearing *en banc*, petitioners suddenly, for the first time, object to the entire edifice of inequitable conduct doctrine. This Court does not sit to consider issues of first impression.

At bottom, it is petitioners who seek a radical departure in the law. Notwithstanding the fact that the Federal Circuit was created as a national court to bring uniformity to our patent system, petitioners attempt to turn back the clock and have this Court review stale "circuit splits" pre-dating the Federal Circuit's creation.

Far from presenting an issue of pressing national importance in which there is deep division within the Federal Circuit, the petition itself demonstrates that the inequitable conduct doctrine is well-settled and is the subject of substantial agreement within the Federal Circuit. In any event, the radical constriction and, ultimately, "abolition" of the inequitable conduct doctrine that petitioners ask this Court to consider is a matter better suited for Congress than the courts (even if petitioners had presented their arguments below, which they did not).

Petitioners' lamentations regarding the supposed "broadening" of the inequitable conduct doctrine over the past twenty years are particularly misplaced in this case. In the district court, respondent Barr Laboratories, Inc. ("Barr") introduced a substantial volume of evidence demonstrating that (1) the applicants had submitted declarations from interested persons without disclosing those interests—*declarations the inventor himself substantially drafted despite the examiner's request for "non-inventor" declarations*; (2) these declarations were material because they were submitted to overcome prior art rejections, and thus went directly to patentability, while the omitted information went directly to the declarants' credibility; and, (3) the applicants' omission of the declarants' interests was plainly intentional. Petitioners, in turn, had ample opportunity to adduce additional facts but declined to do so. The district court's finding of inequitable conduct was compelled by the undisputed facts, and the Federal Circuit's affirmance was likewise compelled by *Refac International Ltd. v. Lotus Development Corp.*, 81 F.3d 1576 (Fed. Cir. 1996), and *Paragon Podiatry Laboratory, Inc. v. KLM Laboratories, Inc.*, 984 F.2d 1182 (Fed. Cir. 1993). However, petitioners failed to so much as question these precedents in their briefing below (including their separate petitions for rehearing *en banc*), and

conspicuously omit any citation to them in their petition for certiorari.

This case also presents no occasion to consider petitioners' purported "conflict" between Federal Circuit precedent and the Patent and Trademark Office's ("PTO's") post-1992 regulations on materiality for the simple reason those regulations are not applicable to this case. The patent-in-suit was prosecuted under the *pre-1992* regulations, which codified the "reasonable examiner" standard employed by the Federal Circuit below. The Federal Circuit here, as in every other case involving patents prosecuted under the pre-1992 regulations, simply applied "the pre-1992 language regarding materiality." App. 10a n.6. Because this case involves the pre-1992 PTO regulations, it presents no issue of continuing importance warranting this Court's review.

For all their hyperbole, petitioners have not presented a single issue worthy of this Court's discretionary review. Given the unique facts of this case and petitioners' failure to identify either an issue of exceptional importance or a genuine conflict within the Federal Circuit warranting this Court's intervention, this case presents no occasion to jettison well-settled precedent or engage in a wholesale revision of the doctrine of inequitable conduct. Thus, the petition should be denied.

COUNTERSTATEMENT OF THE CASE

A. Factual Background

United States Patent No. 5,407,398 ("the '398 patent") claims the oral administration of "1-deamino-8-D-arginine vasopressin," commonly known as DDAVP or desmopressin. App. 2a. Ferring was the exclusive licensee of U.S. Patent No. 3,497,491 ("the '491 patent" or "Zaoral patent")—which claimed the DDAVP compound itself—and had been manufacturing and marketing desmopressin acetate products for intranasal and

intravenous administration since the 1970's. *See id.* at 3a; Fed. Cir. Joint Appendix ("J.A.") 2189.

Shortly before the expiration of the Zaoral patent (and, with it, Ferring's monopoly), Ferring filed the first of several patent applications that ultimately issued as the '398 patent. *See* J.A. 4497. The '398 patent issued on September 10, 1991, after a lengthy prosecution that included multiple rejections by the PTO and an unsuccessful appeal to the Board of Appeals & Interferences ("the Board"). The application resulting in the '398 patent was the third one filed by petitioner Ferring and inventor Hans Vilhardt claiming the same invention, the first two having been rejected. App. 3a & n.1. After the first two rejections, Vilhardt—represented by Ferring counsel—appeared at a preliminary interview regarding the third application and disputed the scope of the prior art. *Id.* at 3a. The PTO "'suggested that applicants obtain evidence from a *non-inventor*' to support their interpretation." *Id.* (quoting J.A. 3460) (emphasis added by the court). Thereafter, Vilhardt submitted declarations from himself and Dr. Paul Czernichow seeking to distinguish the prior art. Although Vilhardt disclosed his own ties to Ferring, Czernichow's 28-page CV failed to mention that he had received research funding from Ferring *that year*. *Id.* at 3a-4a. [1]

Despite the declarations, the examiners rejected claims based on the prior art (specifically Ferring's '491 patent), noting that "'[a]s Applicants are the exclusive licensee of the Zaoral ['491] patent, it is *obviously expeditious* for Applicants to argue that "peroral" referred

---

[1] At the time of his declaration, Czernichow was funded by Ferring for his desmopressin research (the drug at issue). J.A. 2901-02. He was researching desmopressin *with the wife of Ferring's CEO*, Dr. Anna Fjellestad, authoring an article with her on that topic. *See* J.A. 2935; J.A. 3816-17; J.A. 3820.

to in the ['491] patent referred only to'" absorption rather than ingestion through the mouth. App. 4a (quoting J.A. 4390) (emphasis added). The applicants requested reconsideration and yet another examiner reaffirmed the rejections, finding the applicants had failed to distinguish the '491 prior art patent. *Id.*

Following an appeal to the Board and its rejection based on the '491 patent in combination with additional prior art (the "Vavra paper"), Vilhardt wrote to Ferring's counsel that "everything now depends on our ability to deal with the Vavra paper." J.A. 3749. In preparing to "deal with the Vavra paper," Vilhardt contacted at least two Ferring consultants regarding additional declaration evidence: Dr. Iain Robinson and Professor Tomislav Barth. Thereafter, applicants submitted additional declarations from Czernichow, Robinson, and Barth to distinguish the additional prior art that, in combination with the '491 patent, had been the basis for a rejection by the Board. App. 5a-6a. Although each of these declarants had extensive ties to Ferring (Robinson was research director from 1985-86 and a consultant from 1986-89, and Barth worked on Ferring projects between 1984-87), these relationships were concealed from the PTO. *Id.* Petitioners have conceded the "applicant knew of the connections between Ferring and Drs. Barth and Robinson, but did not disclose them." Aventis Fed. Cir. Reh'g Pet. 5.

Although the examiner specifically requested "*non-inventor*" declarations, it is undisputed that Vilhardt substantially drafted the declarations. App. 6a-7a; *see also* J.A. 5544-45; J.A. 3756. "Vilhardt admitted that he gave Barth 'some lines,' telling him "what he should describe in the affidavit." App. 7a (quoting J.A. 5544). Likewise, Robinson conceded that he did not author

portions of his declaration. *See* J.A. 2868.[2] And Czernichow conceded he also did not write all parts of his declaration. *See* App. 24a n.16. Indeed, apart from his signature, Czernichow did not write *anything* in either of his two declarations to the examiner. *See* J.A. 2902; J.A. 2922; J.A. 2925. It is undisputed that the PTO was unaware of Vilhardt's role in drafting the supposedly "non-inventor" declarations. *See* App. 7a.

Following the submission of these declarations, the PTO finally allowed the applicants' claims. *Id.* Nothing in the file history offers any explanation for the PTO's change in position, except Ferring's submission of the declarations. *See id.*; J.A. 3719.

B. District Court Proceedings

Petitioners sued Barr for infringement pursuant to 35 U.S.C. § 271(e). Petitioners' privilege logs, disclosed during litigation, confirmed that Czernichow, Robinson, and Barth were "Ferring Consultants." App. 15a. Although Vilhardt initially denied having contact with these declarants, "when confronted with the privilege log" indicating that "he had contacted each of the declarants and that he sent Barth and Robinson 'draft declarations,'" he recanted, *id.* at 24a, thereafter acknowledging his substantial role in prosecuting the '398 patent, *see* J.A. 5544-45. Indeed, documents petitioners attempted to

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[2] At the time of his PTO declaration, Robinson admittedly had no "particularized expertise" in desmopressin, and had performed no research on drug delivery systems or on the absorption of peptides into the gastrointestinal tract. J.A. 2871. He subsequently expressed surprise that he had been asked to submit such a declaration, adding that he had "no idea" why he was contacted for a declaration or that his declaration would be used to help Ferring obtain a patent. J.A. 2868-69. Indeed, at his deposition, Robinson specifically contradicted the statement in his declaration regarding the Vavra paper. J.A. 2877.

withhold as privileged confirmed Vilhardt's role in obtaining the declarations, as well as his understanding of the importance of the declarations to obtaining the patent. *See* J.A. 5544-45; J.A. 3749; J.A. 5516.

The undisputed evidence also demonstrated that Vilhardt was aware of the declarants' relationships with Ferring. Specifically, "Vilhardt was aware that Robinson was Ferring's pre-clinical research director while Vilhardt was serving as a consultant to Ferring" on the very drug at issue. *See* App. 19a. Likewise, Vilhardt was aware of Barth's affiliation with Ferring. *See* App. 20a.[3]

Barr moved for summary judgment based on inequitable conduct and non-infringement and submitted the following undisputed evidence:

- Ferring's applications had twice been rejected based on the Zaoral patent. J.A. 4514; J.A. 4544.
- The examiner characterized the applicants' arguments trying to distinguish Zaoral as "*expeditious*" given their "obvious[]" interest in the matter. J.A. 4390 (emphasis added).
- Applicable PTO guidelines provided that a declarant's interest is a factor the examiner may consider. Manual of Patent Examining Procedure ("MPEP") § 716(3) (1983-1987).
- In considering Ferring's third application, the examiner requested "evidence from a non-inventor to the same effect." J.A. 3460.

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[3] Ferring concedes that Barth worked in Vilhardt's laboratory. *See* App. 20a; Ferring Fed. Cir. Br. 28. As noted above, Aventis concedes that Vilhardt knew of the connections between Ferring and both Barth and Robinson, but did not disclose them to the PTO. Aventis Fed. Cir. Reh'g Pet. 5.

- The applicants and their attorneys submitted Vilhardt's declaration and CV, which disclosed his former employment relationship with Ferring. J.A. 3531; J.A. 3589.
- At the same time, applicants submitted Czernichow's declaration and *28-page* CV without mentioning his history as a Ferring consultant. J.A. 2901-02; J.A. 3601-32; J.A. 3755.
- The application was again rejected and the Board affirmed based on Zaoral and the Vavra paper. J.A. 4390-91; J.A. 3096-3105.
- To overcome the Board's Vavra-paper rejection, Ferring submitted additional declarations criticizing that reference from Czernichow, Barth and Robinson (who was not even an expert in the relevant field, *see* J.A. 2871, and later contradicted his declaration, J.A. 3703; J.A. 2877), all without disclosing their former employment and consulting relationships with Ferring. J.A. 3701-08.
- The inventor, Vilhardt, *drafted all or some of the so-called "non-inventor" declarations* provided by Czernichow, Robinson, and Barth. *See* J.A. 3756-57; J.A. 2902; J.A. 2922; J.A. 2868; J.A. 5544.

In response to Barr's motion, petitioners failed to submit *any evidence whatsoever* (such as a simple declaration from Vilhardt) to rebut Barr's *prima facie* case or otherwise suggest a good faith explanation for the applicants' actions, effectively conceding that there were no factual disputes.

From these undisputed facts, the district court granted summary judgment to Barr on inequitable conduct. Applying the Federal Circuit's decisions in *Refac* and *Paragon*, it concluded that the applicants' failure to disclose the declarants' interest was material and drew the only *reasonable* inference the summary judgment record would allow—that the applicants' omission of the

declarants' interest was intentional. The district court observed that a finding of materiality and intent was not, in and of itself, enough. The court must "then go on to determine 'whether the applicant's conduct is *so culpable* that the patent should be held unenforceable.'" App. 68a (quoting *Dayco Prods.*, 329 F.3d at 1363). Here, the district court found, based on the undisputed facts, that "[t]he deceit was practiced over a long period of time by more than one person and appears to have been outcome determinative." *Id.* at 68a-69a. Because "the entire record presents clear and convincing evidence of an intent to mislead the examiners, even viewing the evidence, as it must be viewed, in the light most favorable to Plaintiff[s]," the district court held the patent unenforceable. *Id.* at 68a.[4]

C. Federal Circuit Proceedings

The Federal Circuit affirmed. The court applied the traditional two-step approach to inequitable conduct. *See* App. 9a. Under that approach, a party alleging inequitable conduct must first make a threshold showing of materiality and intent. Then the district court must balance both showings and determine, within its discretion, whether when considered together they constitute inequitable conduct. Here, the court of appeals reviewed the district court's "determination that there were no genuine issues of material fact with respect to the issues of materiality and intent" *de novo*, while the overall finding of inequitable conduct was reviewed for an abuse of discretion. *Id.* at 10a, 25a.

With respect to materiality, the court observed that the rules for PTO examiners specifically recognize that

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[4] The district court also granted summary judgment to Barr on non-infringement. The Federal Circuit did not reach that independent holding, which would provide an alternative ground for affirmance. *See* App. 9a & n.5.

"'[a]ffidavits or declarations should be scrutinized closely,'" and that "'[t]he affiant's or declarant's interest is a factor which *may be considered*.'" App. 11a-12a (emphasis added) (quoting MPEP); *see also id.* at 62a. Citing *Refac* and *Paragon*, the court concluded "a declarant's past relationship[] with the applicant are material if (1) the declarant's views on the underlying issue are material and (2) the past relationship to the applicant was a significant one." *Id.* at 13a-14a. The Federal Circuit agreed with the district court that the declarations were "highly material" because they were relied on by the PTO to overcome patentability objections. *Id.* at 14a. The court further agreed that the past relationships were significant—they were not isolated and were not confined to the distant past. *Id.* at 15a-16a. The identities of the declarants would have been significant to the examiners because they "specifically requested 'non-inventor' affidavits." *Id.* at 16a. Based on the totality of the record, the Federal Circuit found it was "clear" that "the examiners were concerned about the objectivity of those providing declarations and their relationship to Ferring, and that they communicated this concern to the applicants." *Id.* at 17a. As in *Refac*, the court found the applicants were on notice as to the materiality of the declarants' ties to Ferring. *Id.* The Federal Circuit rejected petitioners' argument that "they could have, at trial, presented evidence to raise a fact issue concerning either the significance of the experts' views or the significance of past relationships." *Id.* Having failed to present such contrary evidence in response to the summary judgment motion, the court held petitioners "cannot raise a genuine issue of material fact by speculating as to what evidence might have been introduced at trial." *Id.*

Turning to the issue of intent, the Federal Circuit declined to "lay down a general rule as to when intent may be or must be inferred from the withholding of material information by an applicant." App. 19a. Rather,

it applied a settled three-part test for determining intent: (1) whether the applicant knew of the information; (2) whether the applicant knew or should have known of the materiality of the information; and (3) whether the applicant has provided a credible explanation for withholding the information. *Id.* (citing *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348,1354 (Fed. Cir. 2005); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed. Cir. 1997)). Here the undisputed evidence demonstrated that the applicants "knew of significant past relationships of at least two of the declarants." *Id.* The undisputed evidence also demonstrated that the applicants were "on notice" that the examiners were concerned about the identity of the declarants. *Id.* at 20a. Finally, petitioners offered no credible explanation whatsoever for the omission. The Federal Circuit rejected unsubstantiated "possible benign explanations" supported by nothing more than attorney argument and raw speculation. *Id.* at 21a; *see id* at 23a. Rather, "in order to create a genuine issue, [petitioners] bore the burden of submitting an affidavit from Vilhardt to contradict the movant's evidence of intent." *Id.* Applying this Court's holding in *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-49 (1986), the court held that petitioners "cannot create a genuine issue by suggestions that Vilhardt *might* have proffered favorable evidence at trial." *Id.* (emphasis in original) (citing *Paragon*, 984 F.2d at 1191). The only reasonable inference to be drawn from the summary judgment record was that "the past relationships were deliberately concealed." App. 24a.

The court reviewed the district court's ultimate finding of inequitable conduct for an abuse of discretion. App. 25a (citing *General Elec. Co. v. Joiner*, 522 U.S. 142, 143 (1997); *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc)). Considering the materiality of the declarations and the declarants' affiliation with Ferring, the fact that there

was not simply a single omission but "multiple omissions over a long period of time—a fact that heightens the seriousness of the conduct," App. 25a-26a, and the evidence of intent, the Federal Circuit held the district court had not "abused its discretion in finding inequitable conduct," *id.* at 26a. Judge Newman dissented.

Petitioners each filed their own petition for rehearing and rehearing *en banc*. The petitions were denied. App. 86a-89a. Although two judges (in addition to Judge Newman) noted that they would rehear the appeal *en banc*, no judge filed a dissent from denial. App. 89a.

REASONS FOR DENYING THE WRIT

The petition is not worthy of this Court's review for three simple reasons. *First*, petitioners' issues were not presented to, much less decided by, the Federal Circuit and are thus waived. The radical restructuring, if not abolition, of the well-settled patent-law doctrine of inequitable conduct is a matter that obviously should be presented to and passed on by the Federal Circuit—*the court specifically created by Congress to provide nationwide uniformity in patent law*—before this Court's intervention is remotely warranted. In any event, petitioners' arguments are better suited to Congress than the courts.

Second, there is no deep conflict within the Federal Circuit's inequitable conduct jurisprudence requiring this Court's intervention. Petitioners' reliance on contrived "circuit splits" from a quarter of a century ago—before Congress created the Federal Circuit to bring uniformity to patent law—is misplaced. Indeed, this case marks nothing more than the application of settled patent-law principles to a unique set of undisputed facts. The applicants engaged in a pattern of deception before the PTO and offered no evidence of a credible explanation for their concealment of obviously material facts. Distilled to its essence, petitioners' charge is that a finding of inequitable conduct is warranted only "where there is real

misconduct before the PTO," Pet. 11, and that the conduct here was not "real misconduct." That claim is refuted by the record and this Court, of course, does not sit to review factual determinations—much less those committed to a district court's sound discretion.

Third, even if there were any merit to petitioners' claim of a conflict between PTO practice and Federal Circuit precedent on the narrow issue of "materiality" (which there is not), this case would present an exceptionally poor vehicle in which to address it. This case involves the PTO's *pre-1992* regulations, which petitioners concede "articulated the same standard for materiality" applied by the Federal Circuit. Pet. 18. Moreover, there can be no serious question that the intentional omissions here—which go directly to credibility of the very declarations submitted to overcome a patentability objection—were material in any meaningful sense of the word.

II. Petitioners' Arguments That The Inequitable Conduct Doctrine Should Be Dramatically Narrowed Or Abolished Were Not Presented Below And Are Waived.

The petition begins and ends with the premise that the inequitable conduct doctrine has "strayed far from [its] equitable roots" and that, as such, the doctrine requires a substantial pruning, if not outright abolition. The problem for petitioners, however, is that they made no such arguments below and thus these arguments are waived. *See, e.g.*, *Sprietsma v. Mercury Marine, a Div. of Brunswick Corp.*, 537 U.S. 51, 56 n.4 (2002); *United States v. United Foods, Inc.*, 533 U.S. 405, 417 (2001); *Pennsylvania Dep't of Corr. v. Yeskey*, 524 U.S. 206, 212-13 (1998); *United States v. Lovasco*, 431 U.S. 783, 788 n. 7 (1977); *United States v. Ortiz*, 422 U.S. 891, 898 (1975). This Court does not sit to dispense such strong medicine when the lower court has not so much as been asked to consider an issue. To the contrary, this Court's

"traditional rule" precludes a grant of certiorari "when the question presented was not pressed or passed upon below," *United States v. Williams*, 504 U.S. 36, 41 (1992) (internal quotations omitted), precisely because the Court "sits as a court of review," not a court of first impression, *Duignan v. United States*, 274 U.S. 195, 200 (1927).

One will search petitioners' court of appeals briefs (as well as their petitions for rehearing and rehearing *en banc*) in vain for even the faintest suggestion that the court should consider the radical realignment of the inequitable conduct doctrine proposed here, much less its abolition. Petitioners never asserted any conflict between the Federal Circuit's inequitable conduct jurisprudence and this Court's decisions in *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), and *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 816 (1945). Indeed, neither case is cited in any of the six briefs (including their petitions for rehearing and rehearing *en banc*) petitioners collectively filed below.

To be clear, petitioners accepted the principles espoused by the court below, just not the application of those principles to these facts. Both petitioners recited the Federal Circuit's precedent governing inequitable conduct, noting that "materiality and intent are questions of fact," Aventis Fed Cir. Br. 21; *see* Ferring Fed. Cir. Br. 41, without suggesting that the "contours" of inequitable conduct had become too broad. Rather, both merely argued that the *evidence* did not support a finding of inequitable conduct under settled precedent. *See* Aventis Fed. Cir. Br. 22-24; Ferring Fed. Cir. Br. 49-52.

Likewise, petitioners never argued below that the Federal Circuit was applying a test for inequitable conduct that conflicted with PTO regulations and practice, and they did not advocate any of the "stricter" standards for materiality that they suggest would be preferable to prevailing Federal Circuit caselaw. To the

contrary, petitioners expressly argued that the "relevant [pre-1992] PTO regulation in force" required application of a "reasonable examiner" standard, Aventis Fed. Cir. Br. 35; *see also* Ferring Fed. Cir. Br. 42—the very standard applied by the Federal Circuit. App. 10a & n.6.

Nor did petitioners raise these broad, sweeping issues in their petitions for rehearing or rehearing *en banc*. Their rehearing petitions argued that: (1) the panel had "misapprehended pivotal facts," Aventis Reh'g Pet. 5, or had mischaracterized the relationship between the applicant and the declarants, Ferring Reh'g Pet. 9; (2) adopted an allegedly new "knew or should have known" standard for assessing intent in contravention of Federal Circuit precedent, Aventis Reh'g Pet. 9; *see* Ferring Reh'g Pet. 9; and (3) misapplied the summary judgment standard, Aventis Reh'g Pet. 11; Ferring Reh'g Pet. 14. At most petitioners suggested that this case was a departure from settled Federal Circuit precedent, not that the so-called "vast modern expansion of the doctrine" should be reconsidered, Pet. 13, much less abolished, *see id.* at 28.

In any event, such an argument is better suited for Congress than the courts. Congress can legislate the doctrine of inequitable conduct "out of existence any time it chooses." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997). However, given the lengthy history of the doctrine—predating creation of the Federal Circuit itself—"[t]he various policy arguments now made by [petitioners] are thus best addressed to Congress, not this Court." *Id.* "Congress is far better equipped than the judiciary to amass and evaluate the vast amounts of data bearing upon an issue as complex and dynamic as that presented here," namely the effect of expanding or contracting the inequitable conduct doctrine on the vitality of the patent system. *Turner Broad. Sys., Inc. v. F.C.C.*, 512 U.S. 622, 665-66 (1994) (internal quotations omitted).

Even if there were any merit to petitioners' arguments (which there is not), the Court should await, as is its custom, the views of lower courts so that an issue is fully vetted and focused before it steps in to settle it. After all, certiorari jurisdiction is "to be exercised sparingly, and only in cases of peculiar gravity and general importance, or in order to secure uniformity of decision." *Hamilton-Brown Shoe Co. v. Wolf Bros. & Co.*, 240 U.S. 251, 258 (1916). The Court's traditional practice of requiring that an issue be presented or passed on before undertaking consideration is all the more warranted here where the court below is specifically charged by Congress with "reducing the potential for widespread uncertainty and nonuniformity" in patent law. *Foster v. Hallco Mfg. Co.*, 947 F.2d 469, 475 (Fed. Cir. 1991). "That objective was one of the fundamental purposes for establishing the Federal Circuit." *Id.* (citing S. Rep. 97-275, 97th Cong., 1st Sess. 5, *reprinted in* 1982 U.S. Code Cong. & Admin. News, 11, 15. H.R. Rep. 97-312, 97th Cong., 1st Sess. 23). Indeed, as this Court repeatedly has made clear, "Congress conferred exclusive jurisdiction of all patent appeals on the Court of Appeals for the Federal Circuit, in order to provide nationwide uniformity in patent law." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 162 (1989) (internal quotations omitted); *see also Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390 (1996). It would thus be extraordinary for this Court to address an issue that falls squarely within the Federal Circuit's patent-law mandate without first obtaining the views of the Federal Circuit on that issue. Because petitioners have waived the issues they now advance, the petition should be denied.

III. The Federal Circuit Properly Applied Settled Patent Law Principles And There Is No Circuit Split.

Petitioners' assertion of a circuit split is a canard. To manufacture their "split," petitioners rely on *twenty-four*

year old cases (and older) in which, prior to the creation of the Federal Circuit, the regional circuits espoused competing standards for assessing materiality and intent in patent cases. However, the Federal Circuit was created precisely to resolve such conflicts and bring uniformity to patent practice. *See Bonito Boats*, 489 U.S. at 162; *Electronics for Imaging, Inc. v. Coyle*, 394 F.3d 1341, 1345 (Fed. Cir. 2005); *Kennedy v. Wright*, 851 F.2d 963, 966 (7th Cir. 1988) ("The Federal Circuit's exclusive jurisdiction under § 1295(a)(1) was created, after all, so that there could be a uniform jurisprudence of patent law."). After its creation, it promptly resolved the conflicts asserted by petitioners.

In *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362-63 (Fed. Cir. 1984), the court identified three different standards for materiality courts had previously employed and held that "the [pre-1992] PTO 'standard' is an appropriate starting point for any discussion of materiality, for it appears to be the broadest, thus encompassing the others, and because that materiality boundary most closely aligns with how one ought to conduct business with the PTO." To be sure, the court did not adopt a rigid approach, recognizing instead that materiality is a threshold issue of fact and that "'materiality' and 'culpability' are often interrelated and intertwined, so that a lesser showing of the materiality of the withheld information may suffice when an intentional scheme to defraud is established," and vice versa. *Id.* at 1363. Likewise, in *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988), the *en banc* Federal Circuit addressed the conflicting standards of "intent" necessary to meet the threshold for proceeding to the second "balancing" portion of the inequitable conduct inquiry. The court held that "a finding that particular conduct amounts to 'gross negligence' does not of itself justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate

sufficient culpability to require a finding of intent to deceive." *Id.* at 876. Simply put, there is no lingering circuit split, much less one of any consequence given the Federal Circuit's virtually exclusive jurisdiction in patent cases.

Moreover, since its decisions in *American Hoist* and *Kingsdown*, the Federal Circuit's inequitable conduct jurisprudence has remained uniform, yielding no deep divisions within that court. On the issue of materiality, the court has consistently applied the reasonable examiner standard to cases involving patents prosecuted under the pre-1992 PTO regulations, *as it did in this case. See* App. 10a & n.6; *see also Dayco Prods.*, 329 F.3d at 1363-64; *Brasseler, U.S.A. I., L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1380 (Fed. Cir. 2001); *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1274 (Fed. Cir. 2001); *Li Second Family Ltd. v. Toshiba Corp.*, 231 F.3d 1373, 1379 (Fed. Cir. 2000). Similarly, the so-called "sliding scale" theory bemoaned by petitioners has not given rise to any intra-circuit conflict. Indeed, the cases cited by petitioners were each decided unanimously. *See* Pet. 21 & n.9 (citing *Abbott Labs. v. Torpharm, Inc.*, 300 F.3d 1367, 1380 (Fed. Cir. 2002); *Novo Nordisk Pharms., Inc. v. Bio-Tech. Gen. Corp.*, 424 F.3d 1347, 1359 (Fed. Cir. 2003); *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1239 (Fed. Cir. 2003); *Critikon*, 120 F.3d at 1257).

Likewise the relevance of whether an applicant "knew or should have known" about the materiality of omitted information to determining intent is a well-settled aspect of the Federal Circuit's inequitable conduct jurisprudence. *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, 439 F.3d 1335, 1341 (Fed. Cir. 2006); *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1346 (Fed. Cir. 2005); *Brasseler*, 267 F.3d at 1376, 1380; *GFI*, 265 F.3d at 1275; and *Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.*, 204 F.3d 1368, 1375 (Fed. Cir. 2000). And with good reason. Absent an objective standard, inequitable

conduct could almost never be proven by circumstantial evidence, despite this Court's repeated admonition that direct evidence is not necessary. However, "[i]t is hornbook law that direct evidence of a fact is not necessary. 'Circumstantial evidence is not only sufficient, but may also be more certain, satisfying and persuasive than direct evidence.'" *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1272 (Fed. Cir. 1986) (quoting *Michalic v. Cleveland Tankers, Inc.*, 364 U.S. 325, 330 (1960)); *see also Paragon*, 984 F.2d at 1189-90 ("'Smoking gun' evidence is not required in order to establish an intent to deceive."). Indeed, proof of an "[i]ntent to mislead [the PTO] does not require direct evidence," *Bristol-Myers Squibb*, 326 F.3d at 1239, and "the facts in inequitable conduct cases rarely include direct evidence of admitted deceitful conduct," *GFI*, 265 F.3d at 1274. Instead, "[i]ntent is generally inferred from the facts and circumstances surrounding the applicant's overall conduct, especially where there is no good faith explanation for a nondisclosure." *M. Eagles*, 439 F.3d at 1341. That is precisely what occurred here. Barr submitted uncontested circumstantial evidence, while Petitioners failed to even submit an affidavit denying that the applicants intentionally concealed the declarants' relationships with Ferring.

Petitioners' contention—repeated throughout the petition—that the information applicants omitted was not material because the PTO would not consider the declarants' bias as current and former Ferring consultants relevant to the patentability issues, is absurd. *See* Pet. 2, 7, 19, 22, 23, 24, 29. As the district court observed, "[t]he reluctance of the PTO to issue the '398 patent was evident. Each affidavit submitted in support of its issuance was thus highly material to the prosecution history." App. 68a. The Manual of Patent Examining Procedure itself makes clear that "[a]ffidavits or declarations should be scrutinized closely and the facts presented weighed with care. *The affiant's or declarant's*

interest is a factor which may be considered." Manual of Patent Examining Procedure § 716(3) (1983-1987) (emphasis added); *see also* MPEP § 716.01(d) (6th ed. 1995) (examiners "assessing the probative value" of a declaration "*must consider . . . the interest of the expert [declaration] in the outcome of the case*") (emphasis added). That should come as no surprise. Under common law stretching back to Blackstone's day, courts have recognized, for example, that it is appropriate to impute bias to prospective jurors in cases involving their private employers. *See, e.g., United States v. Wood*, 299 U.S. 123, 138 (1936) (citing Blackstone); *Crawford v. United States*, 212 U.S. 183, 195-96 (1909) (same). Thus, far from being "tangential," Pet. 22, these declarations were submitted *to overcome a patentability objection* that had resulted in numerous previous denials. The declarants' credibility was integral to the PTO's decision to allow the patent finally to issue. The PTO had clearly requested non-biased "non-inventor" declarations. The applicants provided the declarations without disclosing the declarants' relationships with Ferring while, at the same time, expressly disclosing Vilhardt's relationship. Worse, the inventor himself *actually drafted the declarations* in whole or in part. This is precisely the kind of concealment or misrepresentation that "has a natural tendency to influence, or was capable of influencing, the decision of the decisionmaking body to which it was addressed." *Kungys v. United States*, 485 U.S. 759, 770 (1988) (internal quotations omitted).

Given the applicants' egregious pattern of behavior and their failure to offer any evidence explaining the withholding of information, the district court in no way abused its discretion in finding the conduct inequitable. Moreover, whether the Federal Circuit (or the district court before it) properly determined that the thresholds for materiality and intent were properly met and that the conduct, considered as a whole, was inequitable, is an inherently fact-bound question. Because "[a] court of law,

such as this Court" is not "a court for correction of errors in fact finding," *Graver Tank & Manufacturing Co. v. Linde Air Products Co.*, 336 U.S. 271, 275 (1949), the petition should be denied.

IV. This Case Presents No Ongoing Conflict Between Federal Circuit Precedent And PTO Regulations Because It Involves The PTO's Pre-1992 Regulations.

This case presents an exceptionally poor vehicle in which to consider petitioners' purported conflict between Federal Circuit precedent and PTO practice for the reason that it involves the PTO's *pre-1992* regulations. As petitioners concede, the pre-1992 version of 37 C.F.R. § 1.56 was "in effect at the time of the prosecution of the patent-in-suit." Pet. 1. Simply put, those regulations have been amended and are inapplicable to patents prosecuted after 1992. Given the limited lifespan of patents, application of the pre-1992 regulations is of little prospective importance. More fundamentally, there is no conflict between the pre-1992 regulations and Federal Circuit caselaw on materiality. To the contrary, the Federal Circuit has adopted the same "reasonable examiner" standard as the starting point in its inequitable conduct analysis. Indeed, the Federal Circuit *expressly applied that standard in this very case.*

A theme throughout the petition is that the Federal Circuit's inequitable conduct jurisprudence "interfere[s] with the PTO's ability to regulate practice before the agency." Pet. 3; *see id.* at 13, 27. But that bold assertion is simply false. The panel opinion could not be clearer: "For patent applications that have been prosecuted prior to 1992, we have held that '[i]nformation is deemed material if there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent.'" App. 10a (quoting *Li Second Family*, 231 F.3d at 1379 (in turn quoting 37

C.F.R. § 1.56 (1989)).[5] The Federal Circuit "use[s] the pre-1992 language regarding materiality for evaluating patents that were prosecuted before [1992]." *Id.* 10a. n.6. Again, thus, petitioners' complaint is not with the standard for materiality articulated by the court of appeals in this case, but with the *application of that standard to these unique facts*. Petitioners concede as much. They note that in *American Hoist* the Federal Circuit adopted the standard invoked below and that the "pre-1992 Rule 56 *articulated the same standard for materiality*." Pet. 18 (*comparing American Hoist*, 725 F.2d at 1362, *with* 37 C.F.R. § 1.56(a) (1991)) (emphasis added).

Plaintiffs' solitary citation for the proposition that the Federal Circuit has declined to apply the PTO's materiality standard is *Digital Control, Inc. v. Charles Machine Works*, 437 F.3d 1309, 1316 (Fed. Cir. 2006). That unanimous decision, however, involved the PTO's *post-1992* regulations, not the regulation at issue here. *See id.* at 1314 (addressing whether "whether the new Rule 56 [is] essentially the same as the 'reasonable examiner' standard" of the old Rule 56). It is far from clear that the post-1992 regulations were intended to supplant the Federal Circuit's standards. In promulgating the new regulation, the PTO noted that: "Section 1.56 has been amended to present a clearer and

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[5] We know from the PTO's own procedures, that the interest of a declarant is necessarily important to a "reasonable examiner" because examiners are instructed that "[a]ffidavits or declarations should be scrutinized closely and the facts presented weighed with care. *The affiant's or declarant's interest is a factor which may be considered.*" MPEP § 716(3) (1983-1987) (emphasis added); *see also* MPEP § 716.01(d) (6th ed. 1995) (examiners "assessing the probative value" of a declaration "*must consider . . . the interest of the expert [declaration] in the outcome of the case*") (emphasis added).

more objective definition of what information the Office considers material to patentability. *The rules do not define fraud or inequitable conduct which have elements both of materiality and of intent.*" Duty of Disclosure, 57 Fed. Reg. 2021-02, 2024 (Jan. 17, 1992) (emphasis added). Indeed, in response to a comment suggesting that courts might interpret the duty of "candor and good faith" to require more than PTO rules require, the PTO stated that the rule was "modified to emphasize that there is a duty of candor and good faith which is broader than the duty to disclose material information." *Id.* at 2025.[6]

Even assuming there were any tension between the Federal Circuit's materiality threshold in the inequitable conduct context and the post-1992 regulations, the Court should await a case involving *those* regulations. That issue is simply not presented here, where the parties, the district court, and the Federal Circuit all agreed that the pre-1992 regulations applied. *See* App. 10a & n.6; App. 61a; Pet.1; Aventis Fed. Cir. Br. 35-36, 41 (noting the "relevant PTO regulation in force at the time of the prosecution of the '398 patent" was 37 C.F.R. § 1.56(a)

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[6] Petitioners' suggestion of a conflict between the doctrine of inequitable conduct and this Court's decision in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001), is misplaced. *Buckman* rejected "*State-law* fraud-on-the-FDA claims" because they "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives," and thus are "impliedly *pre-empted* by, federal law." *Id.* at 348, 350 (emphasis added). The inequitable conduct doctrine arises out of *federal* law. And it does not, in and of itself, make an applicant *liable* for his fraud on the PTO. Rather, the court's authority to render a patent unenforceable for inequitable conduct is founded in the equitable principle that "'he who comes into equity must come with clean hands.'" *Dayco Prods.*, 329 F.3d at 1364 n.3 (quoting *Precision Instrument*, 324 U.S. at 814).

(1991)); Ferring Fed. Cir. Br. 42. In any event, the Federal Circuit *unanimously* decided *Digital Control* only a few months ago, after having deferred the issue for many years. *See, e.g., Dayco Prods.*, 329 F.3d at 1364; *Duro-Last, Inc. v. Custom Seal, Inc.*, 321 F.3d 1098, 1109-10 (Fed. Cir. 2003); *PerSeptive Biosys., Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1322 n. 2 (Fed. Cir. 2000); *Upjohn Co. v. Mova Pharm. Corp.*, 225 F.3d 1306, 1312 (Fed. Cir. 2000); *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1179 n. 8 (Fed. Cir. 1995). No decision in the intervening months has questioned that holding. As such, this Court's intervention would be premature and the petition should be denied.[7]

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[7] If the PTO believes that the Federal Circuit's recent unanimous decision in *Digital Control* is in conflict with its post-1992 regulations, it knows how to make its views known to that court (and, for that matter, this Court). Given that this case does not even implicate the PTO's post-1992 regulations, there is no basis for burdening the Solicitor General by requesting his views on this wholly private dispute.

CONCLUSION

For the foregoing reasons, this Court should deny the petition for writ of *certiorari*.

Respectfully submitted,

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September 22, 2006

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No. 06-372

IN THE

SUPREME COURT OF THE UNITED STATES

FERRING B.V., PETITIONER,

–AND–

AVENTIS PHARMACEUTICALS, INC., PETITIONER,

v.

BARR LABORATORIES, INC., RESPONDENT.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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October 3, 2006

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CORPORATE DISCLOSURE STATEMENT

Petitioners' corporate disclosure statement was set forth at page *ii* of their Petition for a Writ of Certiorari, and there are no amendments to that statement.

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Contrary to Barr's misleading rhetoric, Petitioners are not requesting "abolition"[1] (Resp. Br. 2) of the inequitable conduct doctrine. Rather, Petitioners are appropriately asking this Court to restore reasonable limits to the judicially-created doctrine, which this Court has applied only once, more than sixty years ago, in a case of egregious misconduct by a patent applicant. *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945). Because the inequitable conduct doctrine has the draconian effect of rendering unenforceable otherwise valid patents, and because the Federal Circuit has transformed the doctrine into a rote defense asserted against virtually every patentee seeking to enforce its intellectual property rights, this case presents important questions of public interest that are long overdue for consideration by this Court.

Barr's opposition brief is most notable for the key points it does not contest. Barr does not dispute that *Precision* is the only case in which this Court has held a patent unenforceable on the basis of misconduct before the PTO; that courts interpreted *Precision* narrowly for at least two decades; that circuit splits on both the "materiality" and "intent" issues that define the doctrine accompanied its expansion beginning in the 1970s; that such expansion of the doctrine beyond *Precision* is justified neither by decision of this Court nor by act of Congress; that the doctrine is based solely on inherent judicial power; and that, as broadly interpreted now by the Federal Circuit, the doctrine has no known counterpart in any other area of administrative law.

The Petition raised these points, supported by a mountain

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[1] In fact, rather than Petitioners, some of the nation's preeminent institutions are urging such a drastic course absent reform. The Petition notes these recommendations (Pet. for Cert. 28-30) to highlight the importance of the specific legal issues presented to this Court.

of authority, to underscore the importance of the questions presented and, correspondingly, the need for certiorari. Rather than challenging these points, Barr argues that Petitioners supposedly failed to raise the relevant legal issues below; that circuit splits on patent issues are no longer relevant; and that this case is not the right vehicle for deciding the questions presented. However, Petitioners' two presented questions (concerning the proper scope of the materiality and intent standards in inequitable conduct cases) track precisely the issues presented to and decided by the courts below. In addition, the acknowledged long-standing circuit splits and demonstrated fissures between the Federal Circuit and the PTO further support review by this Court.

Finally, Barr attempts to obscure the significant legal issues raised here by devoting much of its brief to a distorted version of the "facts," which are not in the lower courts' opinions and which are, for the most part, beside the point here. This case clearly presents the Court with an excellent and much needed opportunity to clarify the inequitable conduct doctrine.

I. Petitioners' Questions Are Properly Presented

The questions presented in the Petition concern the scope of the materiality and intent showings required to establish inequitable conduct. These issues were squarely presented to the Federal Circuit and were at the heart of that court's decision. Indeed, almost all of the legal analysis in the majority opinion (App. 10a-24a) is devoted to the scope of the materiality and intent standards.

The Federal Circuit understood that Petitioners were espousing a "narrow view of materiality" that does not encompass information about past personal and professional relationships having no bearing on the substantive issues of patentability. (App. 13a.) The Federal Circuit rejected

Petitioners' materiality standard in favor of one that allows information about a declarant to be considered material if the information might be considered relevant for impeachment purposes under the "general law of evidence." (App. 11a.) This reasoning, articulated and applied by the majority below, set an extremely low threshold for materiality, and it is precisely this holding for which Petitioners seek review.

Similarly, the intent issue raised in Petitioners' second question—whether the intent necessary for inequitable conduct can be based as a matter of law on a "should have known" standard—clearly was briefed and decided below. Petitioners' briefing at the court of appeals expressly argued that mere "oversight" or "negligence . . . would not satisfy the legal requirements for inequitable conduct intent." (Ferring Fed. Cir. Br. 51-52.) Nevertheless, the Federal Circuit held on summary judgment that the requisite intent threshold can be met as a matter of law where an omission is deemed to be "highly material" and the patent applicant "knew or should have known" of the materiality of the omission. (App. 19a.) In a dissent that Barr utterly fails to address, Judge Newman specifically objected to the majority going "too far" in holding as a matter of law that deceptive intent may be established based on "what an inventor 'should have known.'" (App. 41a.) And in seeking rehearing below, Petitioners again argued that the intent element of inequitable conduct cannot be established as a matter of law on the basis of a negligence or "should have known" standard. (Aventis Fed. Cir. Reh'g Pet. 8-10.)

Barr's procedural default arguments also disregard the nature of a petition for certiorari. Certiorari petitions are directed, not to the merits of the case, but rather to the importance of the questions presented, the existence of conflicting authorities, and other factors that demonstrate the need for Supreme Court review. This Court's own rules require certiorari petitions to brief matters—such as the

importance of the issues presented and the need for Supreme Court review—that are not the focus of a merits brief in a Court of Appeals. *See* Sup. Ct. R. 10 & 14.1(h); *see also* ROBERT L. STERN ET AL., SUPREME COURT PRACTICE 354 (7th ed. 1993) (noting a certiorari petition is "unlike any other form of appellate advocacy" because the "question at the certiorari stage is where and when the Court ought to be making law") (internal quotations omitted). Thus, the Petition in this case recites the historical development of the inequitable conduct doctrine, the acknowledged splits between the Federal Circuit and other regional circuits, and the tension between the Federal Circuit's inequitable conduct doctrine and the PTO standards governing the patent prosecution process.[2]

II. The Dramatic Expansion of the Inequitable Conduct Doctrine, Circuit Splits, and Inconsistent Federal Circuit Doctrine Warrant Certiorari

Barr cannot dispute that, under Federal Circuit law, the inequitable conduct doctrine has been dramatically expanded

[2] Barr's reliance on Supreme Court precedent to support its waiver argument (*see* Resp. Br. at 13) is misplaced. This Court granted certiorari in all of the cases Barr cites, and the issues the Court declined to review in each related to legal issues separate and distinct from those raised below. For example, in the first case Barr cites, *Sprietsma v. Mercury Marine*, 537 U.S. 51, 56 n.4 (2002), the Court declined to consider whether federal maritime law governed a tort action where the case had been litigated below under state tort law and the only federal issue previously raised involved statutory preemption. Similarly, the Court did not hint in any of Barr's other cited cases that a certiorari petition is barred from citing a broad set of legal materials to demonstrate the importance of the legal issues litigated below. There also is no merit to Barr's suggestion that, because patent infringement appeals are heard by a single court, this Court should apply a heightened standard in such cases in determining whether an issue was vetted sufficiently below. (*See* Resp. Br. 16.)

from the doctrine recognized in *Precision* and *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944). This Court held the patents unenforceable in *Precision* because the inventor had concededly committed perjury in filing a false oath about the scope of his invention and in *Hazel* because applicant's counsel had fabricated an article cited to both the agency and the courts in support of patentability. Thus, this Court has held patents unenforceable only where there were misrepresentations directly impacting patentability, and those misrepresentations were knowingly and willfully made.

Here, however, the Federal Circuit held that omissions regarding prior relationships between certain of the declarants and Ferring were "highly material" (App. 16a), even though they did not bear on patentability, and that those omissions constituted inequitable conduct under a "should have known" standard of intent. Indeed, the substance of the declarations was unchallenged and was supported by an additional declarant with no previous relationship with Ferring.[3] Barr, however, fails to distinguish between the materiality of the *substance of the declarations* and the materiality of the undisclosed prior connections between three of the declarants and Ferring. (*See* Resp. Br. 2, 20.)

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[3] Barr's extensive characterization of the "facts" fails to mention that the applicants supported their positions with declarations from Dr. Myron Miller, a widely published researcher who had no connections with Ferring, past or present. (*See* App. 4a, 6a.) Barr further asserts that the inventor substantially drafted the declarations in dispute in whole or in part (Resp. Br. 2). This was not a basis for the Federal Circuit's materiality finding (*see* App. 13a-18a), and with good reason: As the Seventh Circuit has observed, "[a]lmost all affidavits submitted in litigation" are not drafted by the affiants. *Russell v. Acme-Evans Co.*, 51 F.3d 64, 67 (7th Cir. 1995). The important thing is that a declarant agree with the statements in a declaration, something not challenged here.

While the scientific information in the declarations may have related to the patentability issue before the PTO, information regarding past employment or research relationships between Ferring and some of the declarants (all "respected non-inventor scientists" (App. 35a)) did not.

Barr also does not dispute that there are circuit splits as to both materiality and intent which pre-date the Federal Circuit, but instead argues that the formation of the Federal Circuit in 1982 resolved all the conflicts. The vigorous dissent below by Judge Newman, the three votes in favor of rehearing *en banc*, the muddled Federal Circuit case law since *Kingsdown* (*see* Pet. for Cert. 20-21), and the widespread criticism of the doctrine of inequitable conduct (*see e.g.*, Pet. for Cert. 12 n.6, 29 n.16) prove otherwise.

Moreover, the Federal Circuit acknowledged earlier this year that information may qualify as "material" under any one of its five different materiality standards. *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1316 (Fed. Cir. 2006). And cases after *Digital Control* confirm the Federal Circuit's disregard of the PTO's standard of materiality even with respect to patent applications filed after 1992. *See Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 176 Fed. Appx. 117, 119 (Fed. Cir. 2006); *Cordis Corp. v. Boston Scientific Corp.*, Nos. 05-1418, 05-1432, 2006 U.S. App. LEXIS 16621, at *6 (Fed. Cir. June 29, 2006); *see also Agfa Corp. v. Creo Prods. Inc.*, 451 F.3d 1366, 1384 (Fed. Cir. 2006) (Newman, J., dissenting) ("The panel majority further states . . . that it need not follow the criteria of the PTO's rule. . . as recently revised. That revision was adopted after public hearings, and exploration of extensive experience as well as the needs and balance of patent examination. That revision binds the PTO and, absent sound reason, the Administrate Procedure Act requires this court to follow it uniformly."). Having multiple materiality standards, as the Federal Circuit does, only creates needless

confusion. *See, e.g., Zoltar Satellite Alarm Sys., Inc. v. Snaptrack, Inc.*, No. C 01-20291 JW, 2006 U.S. Dist. LEXIS 46486, at *9-12 (N.D. Cal. July 10, 2006) (court required patentee to assess materiality using all five standards).

Barr's attempt to dismiss the regional circuit splits as "stale" also ignores that this Court has pointed to circuit splits pre-dating the creation of the Federal Circuit as a valid reason for granting certiorari. *See Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 60 (1998). Moreover, notwithstanding the formation of the Federal Circuit, there remain instances in which other appellate courts may encounter patent law issues. *See Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 839 (2002) (Stevens, J., concurring) (noting that "other circuits will have some role to play in the development of [patent] law" and that "[a]n occasional conflict in decisions may be useful in identifying [patent] questions that merit this Court's attention").

Finally, Barr contends that Congress is better suited to decide the scope of the inequitable conduct doctrine. Yet the very case cited by Barr demonstrates that this Court is willing to decide the scope of non-constitutional doctrines, even though in all such cases Congress could legislate the doctrine "out of existence any time it chooses." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997) (ruling on the scope of the patent doctrine of equivalents). Moreover, it is especially appropriate for this Court to make clear the scope of a doctrine it created as an exercise of inherent judicial power.

III. The Long-Running Conflict between the PTO and the Federal Circuit Justifies Certiorari Here

Barr errs fundamentally in arguing that this Court should wait for a different inequitable conduct case because this one "involves the PTO's *pre*-1992 regulations." (Resp.

Br. 21, emphasis in original.) Inequitable conduct cases are *not* brought pursuant to agency rules and are *not* brought to enforce agency rules. Rather, the inequitable conduct doctrine is based on inherent judicial power to enforce the "equitable maxim that 'he who comes into equity must come with clean hands.'" *Precision*, 325 U.S. at 814. The standard of materiality is judicially controlled.

Nevertheless, in fashioning the judicial standard of materiality, courts may—and indeed should—look to the agency's rules and pronouncements in making a pragmatic judgment about what information is material to the agency's processes. In this case, the PTO's pre-1992 rule defined materiality to include information that "a reasonable examiner would consider . . . important" in deciding whether to allow a patent to issue. 37 C.F.R. § 1.56(a) (1991). In 1992, the PTO revised Rule 56 "to present a clearer and more objective definition of what information the Office considers material to patentability." Notice of Final Rulemaking, Duty of Disclosure, 57 Fed. Reg. 2021-02, 2024 (Jan. 17, 1992). The revised rule specifies that information is material if it is not "cumulative" and helps to establish a "*prima facie* case of unpatentability." 37 C.F.R. § 1.56(b) (2006).

Soon after the rule change, the PTO Commissioner who oversaw the rulemaking justified the change on the ground that the old "rule 56 was indeed too imprecise, and could, and probably was, leading to unjustifiable charges of inequitable conduct in litigation." Harry F. Manbeck, Jr., *The Evolution and Issue of New Rule 56*, 20 AIPLA Q.J. 136, 140 (1992). But even at that time, there was some worry that the Federal Circuit would refuse to modify the judicial standard applied in inequitable conduct cases: "Only time will tell what the courts will do with the rule—whether they will follow it or not in considering questions of unenforceability." *Id.* at 143.

The Federal Circuit, however, has demonstrated its intent to maintain a broad and vague judicial standard of materiality notwithstanding the PTO's clarification of its standard. As set forth in the decision below (App. 11a n.6), the Federal Circuit has already held that the "'reasonable examiner' standard and [the] case law interpreting that standard were not supplanted by the PTO's adoption of a new rule 56." *Digital Control*, 437 F.3d at 1316. Consequently, the conflict between the Federal Circuit and the PTO presented by this case is identical to the conflict that would have been presented if the post-1992 rule had governed the prosecution of the patent-in-suit. This case, therefore, does indeed present an issue of continuing importance and an excellent vehicle for review of the inequitable conduct doctrine.[4]

The PTO's 1992 clarification of its materiality standard parallels a circumstance that this Court confronted in *Raquel v. Education Management Corp.*, 531 U.S. 952 (2000), where the Petitioner had been held by the court of appeals (then-Judge Alito dissenting) to have made a willful misstatement on the form for registering a copyright. On a petition for certiorari, this Court called for the views of the Solicitor General (CVSG). In response, the Copyright Office published a clarification of its administrative practice supporting the Petitioner's view that it had properly

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[4] Barr points repeatedly to the PTO's Manual of Patent Examining Procedure (MPEP), but that reference merely demonstrates the conflict. The MPEP told examiners to consider the declarant's "interest," MPEP § 716(3) (1983-1987), and more recent editions have made clear that "interest" refers to "the interest of the expert in the outcome of the case." MPEP § 716.01(c), at 700-288 (8th ed., rev. 5 2006). The experts here had no interest in the outcome of the case, and the Manual does not even hint that the expert's past relationships with the applicant should be disclosed.

disclosed the information necessary to register a copyright, and the Solicitor General recommended that this Court grant the petition, and vacate and remand the case for reconsideration in light of the views expressed in the Copyright Office's clarification. *See* Br. for the United States as Amicus Curiae in No. 99-1489, 17-19 (available at http://www.usdoj.gov/osg/briefs/2000/2pet/6invit/1999-1489.pet.ami.inv.pdf). This Court took that precise course of action. *See Raquel*, 531 U.S. at 952.

In summary, *Raquel* demonstrates that a court may consider an agency's clarification of its procedures when evaluating whether a procedural wrong has occurred, even where that clarification occurs after the administrative process is complete. *Raquel* also underscores the value of the CVSG process in confirming that a court's holding conflicts with the reality of an agency's processes. Accordingly, even though the 1992 PTO rule itself shows the agency's longstanding conflict with the Federal Circuit, a CVSG would provide the Court with additional information regarding the PTO's processes.[5]

CONCLUSION

For the reasons stated in the Petition and this reply, the Petition for a Writ of Certiorari should be granted.

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[5] This Court has recently used the CVSG process with greater frequency in patent cases, including "private disputes," contrary to Barr's contentions (*see* Resp. Br. 24 n.7). A good example is *Microsoft Corp. v. AT&T Corp.*, 126 S. Ct. 1901 (2006). Unlike here, no circuit split was alleged in that case and, prior to the filing of the SG's brief, the government had not indicated disagreement with the Federal Circuit. *See* Br. of the United States as Amicus Curiae in No. 05-1056 (filed Sept. 29, 2006).

Respectfully submitted,

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No. 06-372

IN THE

Supreme Court of the United States

FERRING B.V. and
AVENTIS PHARMACEUTICALS, INC.,

Petitioners,

v.

BARR LABORATORIES, INC.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

MOTION OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION FOR LEAVE TO FILE A BRIEF AS *AMICUS CURIAE* AND BRIEF *AMICUS CURIAE* IN SUPPORT OF THE PETITION FOR WRIT OF CERTIORARI

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MOTION FOR LEAVE TO FILE AN *AMICUS CURIAE* BRIEF SUPPORTING THE PETITION FOR CERTIORARI

Motion for Leave to File Amicus Curiae Brief of the Biotechnology Industry Organization

The Biotechnology Industry Organization ("BIO") respectfully moves this Court, pursuant to Rule 37.2(b), for leave to file a brief as *Amicus Curiae* in support of the Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit. Petitioners have consented to the filing of this brief, but Respondent has declined to consent, thereby necessitating this motion. A copy of the proposed amicus curiae brief is attached.

As more fully explained at page 1 of the attached brief, under "Interest of Amicus Curiae," BIO is a voluntary association of biotechnology industry companies with a strong interest in the strength and predictability of the United States patent system. BIO seeks leave to file this brief on the status of the standards applied for the defense of inequitable conduct, the disproportionate effect the current state of the law has on the biotechnology industry in particular, and the need, from this industry's perspective, for clarification and certainty on this subject.

For these reasons and those set out in the accompanying brief, BIO hereby moves the Court to allow it to appear as Amicus Curiae, and to submit its brief urging the Court to grant the Petition.

Respectfully submitted,

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BRIEF OF BIOTECHNOLOGY INDUSTRY ORGANIZATION AS *AMICUS CURIAE* IN SUPPORT OF PETITION FOR CERTIORARI

STATEMENT OF INTEREST OF *AMICUS CURIAE*[1]

The Biotechnology Industry Organization ("BIO") is a trade association consisting of more than eleven hundred member companies, academic institutions, and biotechnology centers. BIO represents and understands the needs, as well as the demanding nature, of the biotechnology industry. This industry provides biotechnology-based products that constitute an important and growing value to the public, from life-saving therapeutics for once untreatable diseases, to cleaner fuels and other environmental-friendly technologies, to heartier and more robust crops to feed a growing world. To create this value, the biotechnology industry invests heavily in research and development.

Patents are vital to the members of BIO. Clear evidence of patent protection attracts the capital necessary for the costly and lengthy development, approval and marketing processes for biotechnology inventions. Therefore, BIO members have an interest in maintaining a strong, stable and viable patent system. BIO is deeply concerned that the Federal Circuit's decision below adversely affects the enforceability of patents.

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1. No counsel for a party authored, in whole or part, this brief. No person or entity other than the *amicus curiae* and its counsel has authored, made any editorial choices regarding or exercised any control over the substance of this brief. Petitioner Aventis Pharmaceuticals, Inc.'s parent corporation Sanofi-Aventis S.A. is a member of BIO. Petitioners Aventis Pharmaceuticals, Inc. itself and Ferring B.V., as well as Respondent Barr Laboratories Inc., are not members of BIO.

BIO has no interest in any of the parties or the outcome of this case.

REASONS FOR GRANTING THE PETITION

SUMMARY OF ARGUMENTS

The decision in *Ferring* highlights, in dramatic fashion, the unjustifiably low standards for materiality and intent that some panels of the Federal Circuit now apply in an inequitable conduct determination. The court below ruled that an important biotech patent was unenforceable based on omissions in declarations about prior relationships that had no bearing on the validity of the patent or the scientific accuracy of the declarants' testimony. The decision provides no limits on the standard for the materiality of information that should be supplied to avoid a finding of inequitable conduct and it infers intent to deceive based on omission alone. The panel decision goes too far and, if permitted to stand, makes the patent application process unpredictable and more costly, and will make the unenforceability of otherwise valid patents uniformly suspect. This is particularly true for the biotechnology industry which suffers from disproportionate levels of patent attacks claiming inequitable conduct.

Further, BIO submits that the *Ferring* decision needs review because it demonstrates the havoc created by the Federal Circuit's differing standards for materiality and intent in determining inequitable conduct. In the last ten years at least five different materiality standards have been applied in an inequitable conduct analysis, drifting towards more liberal standards of materiality and lower thresholds of intent. Applicants and patent holders need to know what standards

apply to their interactions with the United States Patent and Trademark Office ("PTO") and how to obtain enforceable patents. The Federal Circuit's rulings, culminating in *Ferring*, provide no such guidance. Rather, they encourage litigation based on hindsight conclusions about omissions and thereby discourage investment in an invention because there is no assurance protectable patent rights can be obtained for high-cost and risky developments like biotechnology products and pharmaceuticals.

The issue is exacerbated by the *Ferring* panel's failure to recognize the collaborative and interactive nature of biotechnology scientists' relationships. In this field, in particular, relationships like those found "material" in *Ferring* are commonplace, necessary and nearly always innocent. The panel decision, by inference, and based on omission alone, ascribes sinister motives to accepted conduct and relationships and then leaps to a legal conclusion of patent unenforceability. The impact of the Federal Circuit's inconsistent application of this area of the law on industry in general, and the biotechnology industry in particular, is profound: more allegations of inequitable conduct by aggressive advocates intent on attacking perfectly valid patents protecting valuable research and development investments; increased litigation expenses, resulting in higher priced products, and increased unpredictability that valid patents will be enforceable, resulting in less investment and less innovation. Ultimately, society is the loser. The Court should grant review.

I. THE FEDERAL CIRCUIT'S MULTIPLE MATERIALITY STANDARDS ARE UNWORKABLE AND FURTHER CONFUSION AND UNCERTAINTY.

A. Patent unenforceability for inequitable conduct was created as the ultimate punishment for truly egregious behavior.

The Court in the 1945 case of *Precision Instrument Mfg. Co. v. Auto Maint. Mach. Co.*, 324 U.S. 806 (1945) first recognized the concept of inequitable conduct as a basis for finding a patent unenforceable. There an inventor of one competing application in an interference proceeding filed a fraudulent affidavit. The opposing party learned of the fraud, but did not inform the PTO. Instead, the parties settled the interference and the submitter of the fraudulent affidavit assigned his rights in his application to the other party. The fraud was uncovered in later patent enforcement proceedings. In this extreme situation, the Court recognized that "inequitable conduct" could so "impregnate the application" to render the patent unenforceable as a matter of law. *See Precision Instrument*, 324 U.S. at 818-19. Hence, as created, this was a narrow doctrine to address egregious behavior. That is not how it is now being applied and, as a result, the inequitable conduct defense has become a favorite defense in patent litigation to attack valid and infringed patents. The Court should grant review to clarify the limits of the doctrine's application.

B. The standards for inequitable conduct have eroded based on inconsistent standards for materiality.

In response to *Precision Instrument*, in 1949 the PTO promulgated its first "duty of candor" rule under 35 U.S.C. § 1.56, which prohibited fraud on the Office. Courts implementing *Precision Instrument* generally found that, as with common law fraud, the representation had to be "material" and "intent to deceive" the PTO had to be proven. However, the courts differed on what standards should be applied to the "materiality" and "intent" elements in determining the existence of "inequitable conduct." As to materiality, there were at least three standards used: an objective "but for" standard as in common law fraud, that is, a requirement that the misrepresentation would have affected the issuance of a patent in any circumstance; a subjective "but for" test, requiring proof that the particular misrepresentation caused the specific examiner to approve the patent application; or a "but it may have" standard, requiring only proof that the misrepresentation "might have" influenced the outcome of the prosecution. *See, e.g., Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362 (Fed. Cir. 1984) (collecting and comparing cases).

In addition to these different standards, in 1977 the PTO sought to clarify its own standard for materiality. The PTO's test for materiality, which was arguably broader than any test adopted by any court to that date, required disclosure of any "material information," defined as information "where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." 37 C.F.R. § 1.56 (1977). In the face of divergent precedent and the PTO's rule, the Federal Circuit could have adopted any number of prevailing

materiality standards in *Am. Hoist & Derrick.* Ultimately, the court adopted the PTO's standard, and for nearly a decade this was viewed as the prevailing standard for "materiality." Inequitable conduct was based on a breach of the applicant's duty of candor to the PTO, rather than any potential misstep that might be viewed as a "misrepresentation" by outsiders to the prosecution process. *See, e.g., Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995).

To clarify the "reasonable examiner" standard of materiality and provide more meaningful guidelines for practitioners, in 1992 the PTO adopted a definition of the phrase "material to patentability" in Section 1.56, delineating a series of guidelines, including whether information is cumulative, establishes unpatentability, or refutes an applicant's position. *See* 35 C.F.R. § 1.56 (2005). The Federal Circuit understood that the PTO intended that the materiality of omissions or disclosures by attorneys to it would be judged in accordance with this new standard. *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358), 1364 (Fed. Cir. 2003) (quoting Duty of Disclosure, 57 Fed. Reg. 2021, 2024 (Jan. 17, 1992) to the effect that rule "has been amended to present a clearer and more objective definition of what information the Office considers material to patentability."); *see also Digital Control, Inc. v. The Charles Machine Works,* 437 F.3d 1309, 1316 (Fed. Cir. 2006) (quoting *Dayco*).

Yet, despite the fact that patent applications have been prosecuted for the last fourteen years under that PTO standard, the Federal Circuit has refused to adopt any single consistent approach to materiality.[2] More recently, a Federal

2. While the patent in suit in *Ferring* was not subject to the PTO's 1992 revisions to Section 1.56, this history is relevant to demonstrate the lack of uniformity in standards before the Federal Circuit.

Circuit panel has held that complying with the requirements set out in Section 1.56 provides no assurance that an entire patent will not be rendered unenforceable based on any of the Court's different "materiality" tests. *See Digital Control, Inc.* at 1315-16. Thus, rather than bringing uniformity to this area of patent law, the Federal Circuit's different rulings have perpetuated a maze of complexity and confusion.

The current unpredictability in application of the inequitable conduct doctrine leaves patent applicants in a quandary and represents a dramatic departure from the intent of *Precision Instruments.* Inequitable conduct is no longer reserved for fraudulent or other egregious conduct, as compliance with the stated rules of the PTO may be inadequate to demonstrate the "clean hands" necessary to defeat a charge of inequitable conduct. As *Ferring* itself shows, mere inferences can be used to satisfy both the "materiality" and "intent to deceive the PTO" requirements, thereby rendering an entire patent unenforceable. *Ferring B.V. v. Barr Labs,* 437 F.3d 1181, 1184, 1191-92 (Fed. Cir. 2006). By the same token, if patent applicants or their counsel provide the PTO with information that is not material to patentability under Section 1.56 but may be deemed material under any one of the five Federal Circuit "materiality" standards, they may still be accused of inequitable conduct because they attempted to conceal the material information from effective review, again rendering the resulting patent unenforceable. In short, applicants are "damned if they do and damned if they don't." This lack of clarity, Federal Circuit inconsistency and dramatic departure from the Court's narrow ruling in *Precision Instruments* are untenable and justify review under Supreme Court Rules 10(a) and (c) to bring certainty to the field.

C. The evaluation of materiality in this case demonstrates the unworkability of the multiple Federal Circuit standards.

The negative impact of the multiple materiality standards being applied by the Federal Circuit is demonstrated in *Ferring*. The examiners suggested the applicant provide declarations of "non-inventors" regarding the meaning of the term "peroral". *Ferring*, 437 F.3d at 1184. They did not request that the applicant supply individuals with no connection at all to the assignee of the applicant's rights. They did not request curriculum vitaes for the affiants. The request was for someone who did not have a direct interest in the outcome of the patent decision.

Even by Respondent Barr's accounts, the applicant met this request. Affiants with impeccable scientific credentials were found and their statements presented in 1986. *Id.*, 437 at 1184 (maj. opinion), 1197-98 (Newman, J., diss.). Four years later, when another rejection was presented, further affiants with similar credentials were asked to address the question. *Id.* 437 F.3d at 1185 (maj. opinion), 1197-98 (Newman, J., diss.). Barr never challenged the veracity of the statements provided and never showed any of the affiants benefited in any way from the patent issuing – rather, the attack on the enforceability of the patent is based on *Ferring's* failure to provide information about prior relationships with the declarants, and the mere possibility that such information could have influenced the examiner's decision to allow the patent to issue.

The panel determined that the applicant "should have" seen beyond the examiners' request that affidavits come from "non-inventors" and construed it as requiring "disinterested"

affiants without "intimate ties to the inventors or Ferring itself." *Ferring*, 437 F.3d at 1190.[3] Apparently that understanding "should have" also extended to voluntary submissions by the applicant four years later in response to a different rejection. That is not what the examiner requested, and goes far beyond the examiners' request for declarations from "non-inventors." Taken literally, the panel's standard would have required declarations from outside experts with no connection to Ferring, the applicants or prosecuting counsel, as anyone with an ongoing relationship to anyone involved with the prosecution would not have been "disinterested." As discussed in further detail in Section II below, this is impractical and contrary to experience in the scientific field.

Even the panel opinion recognizes that it would strain credulity for members of the scientific community to avoid interaction and not call on colleagues to assist with patent prosecutions in appropriate circumstances. *Id.*, 437 F.3d at 1194-95. Nonetheless, this decision states that "at least where the objectivity of the declarant is an issue in the prosecution [which is apparently any time an affidavit is submitted, based on the remainder of the case], the inventor must disclose the known relationships and affiliations of the declarants so that those interests can be considered in weighing the declarations." *Id.*, 437 at 1195. Based on *Ferring's* outcome, moreover, the failure in any prosecution at any time not to declare any such relationship is a material omission as a matter of law.

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3. The panel supported this view of what an applicant should have understood in 1986 based on a case announced in 1996. *See Ferring*, 437 F.3d at 1189-90 (discussing *Refac Int'l, Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576, 1581-82 (Fed. Cir. 1996)).

This new "standard" leaves only more questions in its wake. What has to be disclosed? Purely personal relationships? A historic relationship unrelated to the subject of the patent? One time service on an advisory panel with the applicant or another person affiliated with the assignee of the patent? Joint collaboration on an otherwise confidential, ongoing project unrelated to the application? A chance meeting or casual conversation at a scientific conference? *Ferring* thus simply adds another layer of investigation and disclosure for applicants and patent prosecutors, rather than providing any meaningful guidance and rule of law

In sum, practitioners were already walking a fine line between too much disclosure by overwhelming examiners with immaterial information and too little disclosure, thereby opening themselves up to repeated accusations of inequitable conduct. *Ferring* made this balance more precarious, if not impossible, to maintain. Supreme Court review is warranted to clarify this issue.

D. The Federal Circuit's intent standard is also inconsistent and confusing.

Materiality is not the only finding necessary to support a conclusion of inequitable conduct. There must also be evidence of intent to deceive. *See, e.g., GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1274 (Fed. Cir. 2001). *Ferring* also perpetuates the confusion in Federal Circuit precedent with respect to the evidence required to establish intent to deceive the PTO. Despite an *en banc* ruling that "gross negligence" in the form of an unexplained omission will not suffice to find intent, cases such as *Ferring* continue to rule that a mere omission alone can support an inference of intent to deceive.

This, in turn, makes any alleged error or omission the target of post-hoc attack for "inequitable conduct," a situation that should not be permitted to continue.

In *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir 1988) (*en banc* in relevant part), the Federal Circuit overruled prior cases holding that an intent to deceive could be inferred from the nature of the omission itself and that "gross negligence" of the applicant rendered any other explanation than an intent to deceive illogical. *Kingsdown* rejected this approach in large part to minimize the assertions of inequitable conduct being leveled at practitioners and applicants for simple omissions. *See, e.g., Ferring*, 437 F.3d at 1196 (Newman, J., diss.). In *Ferring*, the district court based its finding of intent entirely on the omissions of the relationships between Ferring and certain declarants. In affirming, the majority found that so long as the applicant "should have" appreciated the materiality of the omission and did not provide a sufficiently "credible explanation," that was enough to support a finding of intent to deceive as a matter of law. *Id.*, 437 F.3d at 1191. The panel applied, in effect, a presumption of malfeasance from the supposed magnitude of the omission. *Ferring* demonstrates precisely why *Kingsdown* rejected the "gross negligence" approach – it is inherently subjective and ignores the realities of patent prosecution.[4]

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4. This is not an isolated aberration. *See, Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1257 (Fed. Cir. 1997), relying on the pre-Kingsdown "should have known" standard of *Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed. Cir. 1984), overruled by *Kingsdown*.*See Kingsdown*, 863 F.2d at 876; *Ferring*, 437 F.3d at 1202. *See also* Lynn C. Tyler, "Kingsdown Fifteen Years Later:What Does It Take to Prove Inequitable Conduct?", 13 Fed. Cir. B.J. 267 (2004) (collecting cases).

This case does not resurrect a stale pre-Federal Circuit split in authority. It highlights the ongoing debate in the Federal Circuit that leaves patent applicants to the chance of what Federal Circuit panel they draw to determine the standards of materiality and intent that will apply to their patents. Supreme Court review is needed to bring clarity and consistency to this important area of the law.

Amicus Curiae respectfully submit that a single, objective standard should apply to finding materiality and intent, and that the presumption of a patent's validity and enforceability should be respected in the inequitable conduct analysis. The Court should grant review.

II. THE HOLDING OF FERRING IMPOSES UNIQUE, COSTLY BURDENS ON THE LIFE SCIENCES COMMUNITY

A. The types of relationships at issue are common in the life sciences community.

The panel decision invalidated a patent based on inferences drawn about relationships that are commonplace, accepted, and even encouraged in the scientific community. Life science research thrives on professional relationships. Scientists in any given specialization tend to have common educational backgrounds, many interpersonal connections, frequently engage in collaborations, and communicate regularly. Such relationships are ubiquitous and multifaceted. They reach across national boundaries, political systems, and cultural barriers just like they transcend the borders of private, public, and academic research. Congress has acknowledged the need to promote cooperative research involving universities, the public sector, and private enterprises by

amending the Patent Act (The Cooperative Research and Technology Enhancement (CREATE) Act of 2004; 108 P.L. 453), and by passing legislation to facilitate public-private research collaborations and technology transfer. The Bayh-Dole Act (96 P.L. 517) and the Stevenson-Wydler Technology Innovation Act (P.L. 96-480), for example, enable Federal agencies to execute license agreements with commercial entities that promote the development of technologies discovered by government scientists, and to enter into cooperative research and development agreements with nonfederal partners to conduct joint research.

In a professional and legal environment that encourages interrelatedness, it is only natural and scientifically reasonable for a life science company to seek to establish relationships with many research groups in its field of interest. Such professional relationships take many common forms, such as basic research collaborations, clinical or field trial participation, speaking engagements, consulting arrangements, grants, postdoctoral support funding, scientific advisory board participation, mentormentee relationships, preceptorships, publication support, transfer of samples, cross-training, industry-sponsored symposia, donations, collegial relationships, and the like.

In the clinical trials area, for example, companies engaged in drug development must often reach out to and establish relationships with large numbers of clinical investigators. For the study of novel breast cancer treatments alone, the National Cancer Institute's website, (http://www.cancer.gov/clinical trial, last visited Oct. 3, 2006) lists 464 open clinical trials as of the writing of this brief, of which 135 are sponsored by industry. Of these, 40 are advanced-stage clinical trials (phase III and IV) that recruit patients at

over 780 clinical centers, hospitals, and clinics in the United States, and at over 770 sites internationally. The magnitude of such research efforts illustrates that relationships between academic and company scientists are a normal and widespread aspect of scientific practice.

Most such relationships involve no exchange of personal remuneration, but focus instead on exchanging information and expertise to advance research projects. In this interactive and fluid professional framework, the question of whether a scientist is "disinterested" or not has little meaning, as the professional relationships at issue in this case illustrate. One declarant, Dr. Czernichow, Professor at the Hopital des Enfants-Malades in Paris, had conducted a clinical study under funding provided by Ferring. *Ferring*, 437 F.3d at 1184; *id.*, at 1198 (Newman, J., dissenting). Another declarant, Dr. Barth, Professor at the Czech Academy of Sciences, had an ongoing joint research relationship with the inventor Dr. Vilhardt. *Id.*, at 1185. Barth and Vilhardt published articles together, spent time in each others' laboratories, and considered each other friends. Some years prior to his declaration, Dr. Barth had apparently conducted studies under a research grant Ferring had provided to his institution, and therefore received occasional financial support to defray the costs of experimental studies in which Ferring was interested. *Id.*, at 1185. A third declarant, Dr. Robinson, division head at the National Institute of Medical Research in London, had briefly been a Ferring employee four years prior to his declaration, and had subsequently had consulting assignments which had ended prior to his declaration. *Id.*

All declarants had respectable scientific credentials, held leading positions at highly-regarded institutions, and received no payment for their statements. It simply strains credulity

to suggest that such scientists would compromise themselves to facilitate the issuance of a United States patent. Nothing in the record so indicates. More distressing to the applicant community, however, is *Ferring's* lack of guidance as to when the cultivation of such unexceptional "ongoing and mutually beneficial relationships," widely occurring in science and falling well within the continuum of common professional interactions, rises to the level of potential bias. The economic and legal uncertainties that now attach to declarations of record in the prosecution histories of thousands of United States patents and pending applications merit review by this Court.

B. The panel decision creates patent uncertainty and increased prosecution costs that will discourage biotechnology investment.

Allegations of inequitable conduct arise with unusual frequency in life sciences cases: approximately 42% of all appeals to the Federal Circuit on the issue of inequitable conduct since the 1988 *en banc* decision in *Kingsdown* involved patents from the biotechnology or therapeutic products sectors[5]. This high frequency of inequitable conduct challenges likely reflects both the high economic value of

5. In preparing this brief, BIO conducted a qualitative survey of published and unpublished opinions in the Federal Circuit, beginning with *Kingsdown* in 1988, that identified 212 opinions in which the issue of inequitable conduct in the PTO was appealed from the lower courts. Of these, 89 involve patents claiming products or methods from the biosciences and biomedical sectors, including agricultural biotechnology, drugs, biologics, medical devices, and diagnostics. These numbers necessarily represent an approximation and do not include appeals that were disposed of by brief orders that do not on their face indicate the nature of the invention at issue, or the legal issues appealed.

life sciences patents, as well as the attractive prospect of being able to capitalize on the patent owner's or licensee's vast investments in bringing the claimed product to market without having to obtain license rights under issued patents.

Few sectors of the United States economy are as dependent upon patents as is the biotechnology industry. It is not uncommon for a biotechnology company to expend hundreds of millions of dollars over more than a decade before collecting its first dollar of product revenue. But investors will not invest where patent rights are increasing by vulnerable to economically inspired accusations of inequitable conduct. Patents are crucial for attracting funding for the development of innovation germinating from university labs and small biotechnology businesses. Without funding, without patents, innovation cannot move from the bench to beneficial applications.

At the patent prosecution level, unfortunately, obtaining patents in biotechnology is costly and increasingly difficult. Not infrequently, applicants need to submit explanatory material and expert declarations to advance their applications. Further costs and uncertainty will now arise from the need to investigate the past, present, or prospective relationships of the declarants to the invention, to the inventor, or to the company or institution to which the invention is assigned or licensed. The applicants' dilemma is worsened by the Federal Circuit's lack of guidance on when a professional relationship purportedly rises to the level of bias such that, absent disclosure, a perfectly valid and infringed patent will be rendered unenforceable.

There are huge consequences to an inference of inequitable conduct, as the life sciences industry is acutely

aware. After decades of research leading to patented products, all could be lost. In *Purdue Pharma L.P. v. Endo Pharms., Inc.* 410 F.3d 690 (Fed. Cir. 2005), *vacated*, 438 F.3d 1123 (Fed. Cir. 2006) for example, the Federal Circuit's eventual reversal of a finding of inequitable conduct was too late to prevent the layoff of approximately half of the patentee's workforce, with serious impact on ongoing drug research programs. Had clear, objective standards of materiality and intent been applied in the first instance, that result could have been avoided.

Almost assuredly the effort and the logistics required in trying to comply with the *Ferring* standards during patent prosecution will tax already limited patent budgets. In effect, decades of issued patents, allowed by habitually reluctant examiners after consideration of expert declarations, are now legally suspect on the basis of professional relationships that are so common in normal scientific practice that researchers would not deem them worthy of special mention. Going forward, even well-meaning and thorough applicants can never be assured that their efforts would satisfy the *Ferring* standards, or any of the five Federal Circuit inequitable conduct "standards."

Yet to justify the vast investment of time and money in experimental products whose likelihood of ever reaching the marketplace is low, companies depend on the strength and enforceability of their patents. It is the certainty that comes from knowing that an invention discovered ten or more years prior to coming to market can be protected that provides the incentive for investors to fund such high-risk, long-term biotechnology products. But investors will not invest where patent rights can be easily subjected to unforeseeable

accusations of inequitable conduct. This profound legal uncertainty, and its chilling effect on life science innovation, deserve the attention of the Court.

CONCLUSION

For the reasons set forth above, this Honorable Court should grant the Petition for Certiorari.

Respectfully submitted,

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IN THE

SUPREME COURT OF THE UNITED STATES

FERRING B.V. AND AVENTIS PHARMACEUTICALS, INC.

Petitioners,

v.

BARR LABORATORIES, INC.,

Respondent.

On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit

MOTION OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* AND BRIEF IN SUPPORT OF PETITIONERS

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MOTION FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE*

Pursuant to this Court's Rule 37.2(b), the Pharmaceutical Research and Manufacturers of America (PhRMA) respectfully request leave of this Court to file the attached brief as *amicus curiae* supporting Petitioners. Respondent has withheld consent to the filing of this brief, thus necessitating the filing of this motion.[1]

PhRMA is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA's members invested an estimated $39.4 billion in 2005 alone toward the discovery and development of new medicines. They are responsible for most of the innovative medicines that have been approved for use in the United States over the past several decades.

Intellectual property principles are of critical importance to PhRMA's members. PhRMA is

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[1] Pursuant to this Court's Rule 37.6, PhRMA states that no counsel for a party authored this motion or brief in whole or in part, and no person, other than PhRMA or its members, made a monetary contribution to the preparation or submission of this brief. A list of PhRMA's members is available at http://www.phrma.org/about_phrma/member_company_list/members/. Petitioner Aventis Pharmaceuticals, Inc. is an affiliate of sanofi-aventis U.S., which is a member PhRMA. Sanofi-aventis U.S. took no part in the preparation or submission of this brief.

interested in ensuring that patent law is applied in a way that promotes the timely development of new medicines, and strong and clear patent rights are essential for further innovation in drug development. The Federal Circuit's uncertain and broadly applied doctrine of inequitable conduct renders patents unenforceable even where the patentee engaged in no activity that violates the duty of candor and good faith before the United States Patent and Trademark Office ("PTO"). This creates an uncertain environment for PhRMA's members undertaking such innovation.

Based on the foregoing, amicus hereby moves to file this brief *amicus curiae* in support of petitioners in this case.

Respectfully submitted,

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The Pharmaceutical Research and Manufacturers of America (PhRMA) submits this brief as *amicus curiae* supporting Petitioners.

INTEREST OF THE *AMICUS CURIAE*

Inequitable conduct is now the defense of last resort in patent cases. As in this case, these assertions are typically founded on the accused infringer's second-guessing of a patent applicant's disclosures to the PTO. Because it is practically impossible for patent applicants to submit all potentially relevant information to the PTO, and because adversaries can always later contend that even innocent statements are nonetheless incomplete or misleading, infringers now routinely resort to charges of inequitable conduct in any attempt to avoid liability. Such allegations are especially pernicious when an infringer's "specific intent" contentions are based only on inference and circumstance. Indeed, because this defense turns entirely on a later assessment of the applicant's subjective intent, a recent study by the National Academies of Science has recommended abolition of the defense in its entirety. *See* Stephen A. Merrill, et al., National Research Council, A Patent System for the 21st Century, 121-23 (2004), http://www.nap.edu/html/patentsystem/0309089107.pdf.

Pharmaceutical companies inordinately suffer the consequences that flow from the Federal Circuit's present inequitable conduct doctrine, not because their conduct in procuring patents differs from other patent applicants, but because the Hatch-Waxman

Act offers the bounty of 180-day exclusivity to any would-be generic manufacturer who succeeds in challenging the enforceability of an innovator's drug patent.[2] 21 U.S.C. § 355(j) (2006). A finding of inequitable conduct has grave consequences for patentees because it renders the entire patent unenforceable. *See, e.g., Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988) (*en banc*). Moreover, accused infringers that win a judgment that a patent is unenforceable have recovered their reasonable attorney fees. *See, e.g., Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 669-70 Cir. 2000) (citation omitted) ("A finding of inequitable conduct can be the basis for awarding attorney fees under [35 U.S.C. § 285].").

Such a judgment also often leads to follow-on antitrust litigation pursuant to *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 174 (1965), in which the accused infringer alleges that the patentee improperly enforced its patent knowing that it was procured by fraud on the PTO in violation of section 2 of the Sherman Act. In such cases, the accused infringer could also win treble damages from the patentee.

Nor are the consequences of inequitable conduct limited to litigation. In one recent example, a

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[2] Approximately forty percent of the patent cases decided in the last three years by the Federal Circuit that address inequitable conduct issues involved pharmaceutical patents.

PhRMA member laid off more than half of its employees after the district court ruled that its patent was unenforceable due to inequitable conduct before the PTO and the Federal Circuit at first affirmed the district court. *See Local Briefing: OxyContin Maker Victorious in Court*, Hartford Courant, Feb. 2, 2006, at E2 (reporting that Purdue Pharma L.P. had "cut its workforce of 3,300 by 1,863" after the district court's ruling); *see also Purdue Pharma v. Endo Pharm.*, 410 F.3d 690 (Fed. Cir. 2005) (affirming the district court), *vacated on panel rehearing*, 438 F.3d 1123 (2006). On rehearing, the same panel of the Federal Circuit ultimately vacated the district court's holding of inequitable conduct, *see id.*, but by then, enormous damage had been done. That the same panel of the Federal Circuit could unanimously reach opposing results in the same case within a few months demonstrates the uncertainty that make this area of the law so destructive.

SUMMARY OF ARGUMENT

Despite the serious consequences that flow from a finding of inequitable conduct, the Federal Circuit and district courts have not adopted any reliable standard for information that a patent applicant must submit to the PTO during prosecution, that is, what information is "material." In fact, the Federal Circuit has set forth no less than five different standards for what is material, effectively nullifying the PTO's definition of what is "material" embodied in its regulations. Consequently, a patent applicant which fully complies with the PTO's requirements can still

be found to have committed inequitable conduct by a court in subsequent litigation.

By ignoring the PTO's definition of material information, the Federal Circuit has misunderstood this Court's decisions regarding an agency's role in defining the rules and procedures that apply in proceedings before it.

By lowering the threshold for a finding of deceptive intent from evidence of specific intent to mere negligence, the Federal Circuit's standard could open all errors of judgment during the prosecution of a patent to charges of inequitable conduct. This approach gives incentive to an infringer to scour the patent file wrapper for any omission that might be through an advocate's hindsight reconstruction of events, be cast as a misrepresentation. The Federal Circuit's approach breeds uncertainty and leads to wasteful litigation in both patent cases and follow-on antitrust cases. The present case typifies this problem.

ARGUMENT

I. The Federal Circuit's Inequitable Conduct Doctrine Has Expanded Beyond its Purpose and Led To Uncertainty And Wasteful Litigation

Courts grappling with the two elements of inequitable conduct ("materiality" and "intent to deceive") have created a patchwork of cases that create uncertainty and substantial burdens for both patent applicants (PhRMA members in particular) and the PTO. Although Congress established the

Federal Circuit to bring consistency to the patent law, that court has presided over an unprecedented growth in the number of cases where charges of inequitable conduct are made, due in large part to the lack of a clear legal standard.

Today, as the petition correctly points out, there are five different legal standards for materiality applied by courts. These include current PTO Rule 56, 37 C.F.R. § 1.56 (2006), its predecessor rule, and three judicially-created standards: the objective "but for" test; the subjective "but for" test; and the "but it may have been" test. *See Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314-15 (Fed. Cir. 2006) (describing five tests for materiality). Notwithstanding a materiality standard promulgated by the administering agency, a patent applicant seeking to comply with its duty of candor is left without clear guidance as to what information should be disclosed to that agency.

The Federal Circuit's approach requires patent applicants to consider each of these standards of materiality in determining what, if any, information should be submitted to the PTO in order to avoid allegations of inequitable conduct in future litigation. *See id.* at 1316. Furthermore, the Federal Circuit's approach is fundamentally unfair because it creates the prospect that an applicant could fully comply with the current law of materiality and still have its patent held unenforceable based on a different standard for materiality applied by the court years down the road.

The patent applicant's burden is further compounded by the Federal Circuit's current sliding scale of deceptive intent. *See, e.g., Abbott Labs. v. Torpharm, Inc.*, 300 F.3d 1367, 1380 (Fed. Cir. 2002) (citation omitted) ("[T]he intent necessary to establish inequitable conduct is based on a sliding scale related to materiality of the omission."). At its extreme, as in this case, this elastic intent analysis permits a court to render a patent unenforceable based upon *mere negligence*, a "should have known" standard.

The Federal Circuit initially required evidence of intentional misconduct. *See Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1383 (Fed. Cir. 1983). But the court has since adopted a sliding scale approach where the greater the materiality, the lower the showing of intent must be such that—as in this case—omissions that are found highly material only require evidence of what amounts to mere negligence to obtain summary judgment. Indeed, the Federal Circuit acknowledged that allegations of inequitable conduct had become so commonplace as to be a "plague" and attempted to clarify the proof required for intent in an effort to address its concern. *See Burlington Indus. Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988). This clarification, however, did not last for long. *See Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1372 (Fed. Cir. 2003) (Newman, J., dissenting).

It is one thing for a fact finder to draw a permissive inference that an applicant acted with intent to deceive based upon a highly material nature

of the statement or omission. It is quite another for a court to conclude as a matter of law, based only on a record submitted in connection with a motion for summary judgment, that an applicant acted with fraudulent intent by not including facts which only now the Federal Circuit has identified to be material. *See Poller v. Columbia Broad. Sys., Inc.*, 368 U.S. 464, 473 (1962) (cautioning against a grant of summary judgment where motive and intent play leading roles).

Even subjective good faith may offer little protection to a charge of inequitable conduct, as the court may find deceptive intent based on its retrospective assessment of what the patent applicant should have known about the materiality of an undisclosed reference. *See A.B. Dick Co. v. Burroughs Corp.*, 798 F.2d 1392, 1398 (Fed. Cir. 1986) ("[A]determination of inequitable conduct will not be avoided if knowledge of materiality or gross negligence greatly outweighs the lack of deceptive intent."). But the doctrine of inequitable conduct is intended to guard against dishonesty in the prosecution of a patent, not errors in judgment.

The uncertainty regarding which materiality standard a court might apply in future litigation, coupled with the "should have known" standard of intent, imposes significant burdens on patentees, requiring them to evaluate every potentially relevant piece of information known to them under a medley of different materiality standards that might ultimately apply. This burden is particularly heavy for PhRMA members because, due to the FDA approval process,

they often engage in further research related to a product after a patent application has been filed, generating significant quantities of additional information that may or may not be material under one of the Federal Circuit's materiality standards.

Moreover, PhRMA members may be aware of vast bodies of literature that may be material under at least one of the Federal Circuit's materiality standards. To avoid a potential finding of inequitable conduct, the applicants may need to review all such information under each of the Federal Circuit's standards and submit to the PTO all of the information that is even arguably material under any of those standards. Thus, the Federal Circuit's approach burdens both patent applicants and the PTO itself, which must review the information submitted by applicants. *See Manual of Patent Examining Procedure* § 609, at 600-141 (8th ed., rev. 5 2006) ("An information disclosure statement filed in accordance with the provisions of 37 C.F.R. 1.97 and 37 C.F.R. 1.98 will be considered by the examiner assigned to the application.").

Nor does full disclosure of all arguably relevant material to the PTO shield patent applicants from allegations of inequitable conduct under the Federal Circuit's approach. Even if an applicant discloses all potentially relevant information under each of the Federal Circuit's materiality standards, the applicant may still face allegations that it committed inequitable conduct by "burying a particularly material reference in a prior art statement containing

a multiplicity of other references." *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1184 (Fed. Cir. 1995).

The potential harm to a patent applicant does not end with a judgment that its patent is unenforceable. Armed with such a judgment, accused infringers often bring follow-on antitrust litigation pursuant to *Walker Process*, 382 U.S. at 174. Such litigation further burdens the courts, and it subjects patent owners to the risk of claims for huge treble damages in follow-on antitrust cases, all predicated on a doctrine that is rife with uncertainty. The current state of affairs cries out for intervention by this Court.

II. The Federal Circuit Has Improperly Ignored the PTO's Standard for Materiality

The petition notes that the Federal Circuit has consistently held, in determining whether information is material for its inequitable conduct inquiry, that it need not follow the PTO's rule that defines materiality, 37 C.F.R. § 1.56(b) (2006). *See, e.g.*, *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314-16 (Fed. Cir. 2006). Indeed, the Federal Circuit has expressly held that neither the PTO's pre-1992 regulation nor the PTO's present regulation "supplant[s] or replace[s]" the Federal Circuit's case law.[3] *Id.* at 1316. Instead, the Federal Circuit has

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[3] Respondent argues that the present rule, which was published in the Federal Register on January 17, 1992, does not apply here because the patent issued on September 10, 1991. This argument might have merit if the PTO's rule prescribed law (continued...)

viewed those regulations as "additional test[s] of materiality" beyond the three judicial standards for materiality that the Federal Circuit applies. *Id.*

The PTO's Rule defines the materiality of information provided or withheld by an applicant as information that is not cumulative to other information of record in the application that

> (1) . . . establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or
>
> (2) . . . refutes or is inconsistent with, a position the applicant takes in:
>
> (i) Opposing an argument of unpatentability relied on by the Office, or
>
> (ii) Asserting an argument of patentability.

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limiting a regulated entity. *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208-09 (1988). However, this Court has limited "retroactive" measures to those that "impair[] rights a party possessed when he acted, increase[] a party's liability for past conduct, or impose[] new duties with respect to transactions already completed." *Landgraf v. USI Film Prods.*, 511 U.S. 244, 280 (1994). The PTO's 1992 rule has no such consequences.

37 C.F.R. § 1.56(b) (2006).[4] No one contends that the information at issue in this case is material under this standard.

By adhering to its own constantly expanding view of materiality to establish inequitable conduct, the Federal Circuit has ignored the function granted to the PTO by Congress, while at the same time ignoring—as properly pointed out in the petition—established principles of administrative law.[5]

In prescribing the "powers and duties" of the PTO, Congress provided that the Office

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[4] The Rule further defines a "*prima facie* case of unpatentability" as "established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden of proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability." 37 C.F.R. § 1.56(b) (2006).

[5] There is no challenge to the validity of the PTO's regulation in this case. The PTO has taken the position that Rule 56 is grounded in 35 U.S.C. § 2(b)(2) (or its predecessor 35 U.S.C. § 6(a)). *See, e.g.*, Duty of Disclosure, 57 Fed. Reg. 2021, 2023 (Jan. 17, 1992). And no one is challenging that assertion. If, on the other hand, a PTO regulation were inconsistent with or based on an impermissible construction of a statute, it would be entitled to no deference. *See, e.g., Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984).

> may establish regulations, not inconsistent with law, which –
>
> (A) shall govern the conduct of proceedings in the [PTO];
>
> (B) shall be made in accordance with section 553 of title 5;
>
> (C) shall facilitate and expedite the processing of patent applications . . . ; [and]
>
> (D) may govern recognition and conduct of agents, attorneys, or other persons representing applicants or other parties before the Office . . . .

35 U.S.C. § 2(b)(2) (2000).

Relying on this statutory authorization and command, the PTO has over the years defined the "Duty to disclose information material to patentability." 37 C.F.R. § 1.56 (2006). By its disavowal of the PTO's regulation, the Federal Circuit has acted in a manner that is inconsistent with this Court's landmark administrative law decisions that set the boundaries between federal agency and federal court authority. *See Vermont Yankee Nuclear Power Corp. v. Natural Res. Def. Council, Inc.*, 435 U.S. 519. 543-44 (1978):

> Absent Constitutional constraints or extremely compelling circumstances, the "administrative agencies 'should be free to fashion their own rules of procedure and to pursue methods of inquiry

> capable of permitting them to discharge their multitudinous duties.'" *FCC v. Schreiber*, 381 U.S. [279,] 290 [1965].

435 U.S. at 543-44, quoting *FCC v. Pottsville Broad. Co.*, 309 U.S. 134, 143 (1940).

The principles of *Vermont Yankee* apply *a fortiori* here because Congress made it clear that the PTO regulations "shall govern the conduct of proceedings in the Office." 35 U.S.C. § 2(b)(2)(A).[6]

This Court's decision in *Precision Instruments Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945), does not support the Federal Circuit's posture on inequitable conduct.

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[6] There are practical reasons that support following the PTO's disclosure rule. In responding to the numerous written comments made on the proposed rule, some of which contended that it should not be adopted because the existing rule was "presently in conformance to the materiality standard being applied by . . . the Federal Circuit," the PTO stated that

> the amendment to § 1.56 was proposed to address criticism concerning a perceived lack of certainty in the materiality standard. The rule as promulgated will provide greater clarity and hopefully minimize the burden of litigation on the question of inequitable conduct before the Office, while providing the Office with the information necessary for effective and efficient examination of patent applications.

57 Fed. Reg. at 2023. The PTO is in a position to decide what information is or is not material.

In that case, the "fraud" was not limited to the PTO and its processes, but included fraudulent behavior in federal courts. It is one thing for a federal court to apply equitable principles to protect the integrity of the judicial process. It is a far different thing for a federal court to review a person's conduct before an agency based upon a different set of standards than the agency itself applies.

Despite the PTO's clear rule, the Federal Circuit has continued to breed uncertainty and prolonged litigation, not only in patent infringement actions, but also in antitrust suits that spring from findings of inequitable conduct. Although the PTO has defined "what information the Office considers material to patentability," 57 Fed. Reg. at 2024, in 37 C.F.R. § 1.56 (2006), the Federal Circuit continues to apply different standards which are, of course, unknowable by the patent applicant at the time he engages in the allegedly improper conduct. *See Digital Control Inc.*, 437 F.3d at 1314-15.

III. The Federal Circuit's Affirmation of Summary Judgment On the Intent Issue Is Emblematic.

This case is the best example of the pitfalls of the present state of the Federal Circuit's doctrine of inequitable conduct. The essence of the judgment of inequitable conduct in this case, as affirmed by the Federal Circuit, is that the applicant did not disclose that certain non-inventor declarants had *prior* relationships with the applicant and that the applicant *should have known* this information was highly material.

Here, the patent applicant submitted declarations, the truthfulness of which are unchallenged, from distinguished experts with impeccable credentials. Based solely upon evidence of an inadvertent omission of past unrelated professional connections -- which may only bear on the relative weight to be given the declarations -- the Federal Circuit found there to be no dispute that the applicant intended to deceive the PTO. In so doing on summary judgment, the Federal Circuit plainly failed to resolve all factual disputes and all inferences in the non-movants favor. *See Hunt v. Cromartie,* 526 U.S. 541, 552 (1999) (district court erred because "it either credited appellees' asserted inferences over those advanced by appellants or did not give appellants the inference they were due.").

Moreover, the Federal Circuit has adopted what amounts to a *per se* rule governing the submission of non-inventor declarations to the PTO. But this new judicial rule brings only greater burden to the patent applicant, and greater uncertainty to the patent system. Patent applicants have little or no control over third parties whose opinions may be sought to aid the PTO in its determinations, and may have difficulty convincing outside experts to subject themselves to personal questioning *even when each and every factual statement in their declarations are indisputable true.* When, as here, patents are struck down even though all of the information submitted to the PTO on the merits of the issue was entirely truthful, the intended incentive of the patent system to reward invention is subverted by a desire to

presume the worst of those seeking otherwise entirely legitimate patent protection. By so doing, the Federal Circuit has only further burdened the PTO and patent applicants and increased the opportunity for mischief.

CONCLUSION

The petition has clearly demonstrated the lack of certainty created by the Federal Circuit's ever-expanding approach to inequitable conduct. This Court's grant of the petition and ultimate clarification of the standards for materiality and intent will return the doctrine to its proper roots.

Respectfully submitted,

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Supreme Court of the United States

FERRING B.V. and
AVENTIS PHARMACEUTICALS, INC.,
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v.

BARR LABORATORIES, INC.,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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MOTION FOR LEAVE TO FILE BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

Pursuant to Rule 37.2 of the Rules of this Court, the Washington Legal Foundation (WLF) respectfully moves for leave to file the attached brief as *amicus curiae* in support of Petitioners. Counsel for Petitioners has consented to the filing of this brief. Counsel for Respondent declined to consent, thereby necessitating the filing of this motion.

WLF is a non-profit public interest law and policy center with supporters in all 50 states. WLF regularly appears before federal and state courts to promote economic liberty, free enterprise, and a limited and accountable government.

In particular, WLF has appeared in numerous federal and state courts in cases raising issues related to health care delivery. *See, e.g., Pharmaceutical Research and Manufacturers of America v. Walsh*, 538 U.S. 644 (2003). WLF successfully challenged the constitutionality of Food and Drug Administration (FDA) restrictions on speech regarding off-label uses of FDA-approved products. *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000). WLF also has participated in numerous court proceedings raising important issues regarding the scope and validity of pharmaceutical patents. *See, e.g., Purdue Pharma, L.P. v. Endo Pharmaceuticals, Inc.*, 438 F.3d 1123 (Fed. Cir. 2006) (opposing efforts to invalidate patent on grounds of inequitable conduct); *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331 (Fed. Cir. 2005), *cert. denied*, 126 S. Ct. 2887 (2006); *Pfizer, Inc. v. Dr. Reddy's Laboratories, Ltd.*, 359 F.3d 1361 (Fed. Cir. 2004); *Allergan, Inc. v. Alcon Laboratories, Inc.*, 324 F.3d 1322 (Fed. Cir.), *cert. denied*, 540 U.S. 1048 (2003).

WLF strongly supports providing patent protection to pharmaceutical manufacturers that develop new and useful drugs. WLF believes that if advances in health care are to continue, it is vital that companies that develop new drugs and medical devices be afforded a substantial period of exclusivity, during which potential competitors are not permitted to market the same product. That exclusivity period provides an economic incentive for new product development by ensuring that pharmaceutical companies that gamble the substantial sums necessary for the development of new therapies will be able to reap substantial rewards in those few instances in which their research and development expenditures bear fruit.

WLF also recognizes that Congress has imposed limits on patent rights and that those limits must be strictly enforced by the courts if competition is to be maintained. Nonetheless,

WLF believes that the Federal Circuit's decisions in this and similar cases – which have invalidated numerous important patents on inequitable conduct grounds – have the potential to undermine our nation's patent system if allowed to stand. WLF is concerned that the Federal Circuit's "inequitable conduct" case law has drifted far afield from its "unclean hands" roots. By lowering the bar for those charging patent invalidity due to inequitable conduct, the Federal Circuit has considerably increased the risks to those asserting patent rights and considerably reduced the market value of all patents. WLF is concerned that if the property rights of patent holders can be so easily eliminated, the public will quickly lose faith in the viability of our patent system.

WLF fully supports Petitioners' request that the Court grant review of both of the Questions Presented in this Petition. WLF writes separately in order to emphasize its particular concern over the first Question Presented and the Federal Circuit's expansion of what constitutes a "material" omission from a patent application.

WLF is filing this brief because of its interest in promoting the stability of the nation's patent system; it has no interest, financial or other, in the outcome of this lawsuit. Because of its lack of direct economic interests, WLF believes that it can assist the Court by providing a perspective that is distinct from that of any party.

For the foregoing reasons, the Washington Legal Foundation respectfully requests that it be allowed to participate in this case by filing the attached brief.

Respectfully submitted,

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October 6, 2006

QUESTION PRESENTED

Amicus curiae addresses the following issue only:

Whether the U.S. Court of Appeals for the Federal Circuit has improperly expanded the scope of the inequitable conduct doctrine by lowering the threshold of what constitutes "material" information that a patentee must disclose to the U.S. Patent and Trademark Office so as to include information that has no bearing on patentability.

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BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

INTERESTS OF *AMICUS CURIAE*

The interests of *amicus curiae* Washington Legal Foundation (WLF) are set forth in the motion accompanying this brief.[1]

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[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, contributed monetarily to the preparation and submission of this brief.

STATEMENT OF THE CASE

This case raises important issues regarding the circumstances under which it is appropriate for federal courts to decline to enforce an otherwise valid patent, on the grounds that the patent holder engaged in inequitable conduct before the U.S. Patent and Trademark Office (PTO).

Petitioners filed suit against Respondent Barr Laboratories, Inc. in 2002, alleging that Barr was infringing a patent issued in 1992 (the "Ferring Patent"). The invention describes a method for orally administering DDAVP (an antidiuretic drug used to treat diabetes insipidus). Prior to the invention, DDAVP was administered only through the nasal passages.

During proceedings before the PTO, an issue arose concerning whether the invention was anticipated by prior art. The examiners suggested that the inventor, Dr. Hans Vilhardt, submit "evidence from a non-inventor" regarding whether an earlier patent (the "Zaoral Patent") suggested oral administration of DDAVP for gastrointestinal absorption. Pet. App. 3a. In response, Vilhardt in 1986 submitted four declarations on that issue – two from himself and one each from Dr. Myron Miller and Dr. Paul Czernichow. *Id.* 3a-4a.

Later, in response to additional concerns raised by the Board of Patent Appeals and Interferences, Dr. Vilhardt in 1990 submitted five additional declarations to the effect that an 1973 article written by Ivan Vavra (the "Vavra reference"), even when read in combination with the Zaoral Patent, would not suggest the gastrointestinal absorption of DDAVP. These declarations were sworn to by the three 1986 declarants, as well as by Dr. Iain Robinson and Dr. Tomislav Barth. *Id.* 6a. There has been no suggestion in these proceedings that any of

the declarations was false. The PTO issued the Ferring Patent without elaboration in September 1991. Vilhardt assigned his patent rights to Petitioner erring B.V., which in turn signed an exclusive licensing agreement with Petitioner Aventis Pharmaceuticals, Inc. *Id.* 3a, 7a.

Petitioners filed suit after Barr announced in July 2002 that it intended to market a generic version of the compound at issue. *Id.* 7a. Barr moved for summary judgment, claiming that its marketing plans would not infringe the Ferring Patent and that the patent was invalid due to inequitable conduct before the PTO. In February 2005, the district court granted summary judgment on both grounds. *Id.* 50a-85a. The court concluded that the PTO "must have relied substantially" on the declarations of Drs. Czernichow, Robinson, and Barth in allowing the Ferring Patent. *Id.* 56a. The court noted that those declarations did not disclose that each of those three individuals had had prior business relationships with Ferring (albeit they had no business relationships at the time they signed their declarations): Dr. Czernichow had (unbeknownst to Dr. Vilhardt) served as a consultant to Ferring, Dr. Robinson had been employed by Ferring and was a friend of Dr. Vilhardt, and Dr. Barth had intermittently worked on Ferring-funded projects (albeit he was never compensated by Ferring). The court determined that their declarations were "highly material," *id.* 68a, and that the three declarants' relationships with Ferring were material as well. *Id.* 64a. It also determined that the failure to disclose those relationships was done with "an intent to deceive" the PTO. *Id.* 67a. The court then determined that the applicant's misconduct was "so culpable that the patent should be held unenforceable." *Id.* 68a.

A divided Federal Circuit affirmed. *Id.* 1a-49a. The appeals court explained that under established Federal Circuit

case law a patent will be declared unenforceable due to inequitable conduct if the alleged infringer can demonstrate that: (1) the applicant made an affirmative misrepresentation of *material* fact, or failed to disclose *material* information to the PTO; (2) the misrepresentation or omission was undertaken with *intent* to mislead; and (3) the applicant's conduct is sufficiently culpable to warrant a determination that the patent should be held unenforceable. *Id.* 9a.[2] The court stated that information is deemed "material" if there is "a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent." *Id.* 10a. The court said that a declarant's past relationship with a patent applicant meets that materiality standard whenever: (1) the declarant's views on "the underlying issue" are material; and (2) the relationship to the applicant "was a significant one." *Id.* 13a-14a. The court determined that those standards had been met in this case. *Id.* 14a.[3] The appeals court's determination that the omissions were "highly" material, *id.* 14a and 18a, included no discussion of the declarations of Dr. Miller. Dr. Miller, whose lack of a relationship with Ferring has never been disputed, largely replicated the opinions contained in the disputed declarations.

The appeals court also determined that the applicant's omissions were made with an intent to deceive. *Id.* 18a-24a. While conceding the absence of any direct evidence of such intent, the court said that intent could be inferred, even at the

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[2] The appeals court stated that the district court's materiality and intent findings were subject to *de novo* review. *Id.* 10a.

[3] The court said that "the omitted affiliation with respect to Robinson in particular was highly material since Robinson had actually been employed by Ferring." *Id.* 25a.

summary judgment stage, when the omitted information is "highly material" and: (1) the applicant knew of the information; (2) the applicant knew "or should have known" of its materiality; and (3) the applicant has not provided "any credible explanation for the withholding." *Id.* 19a. The court said that all those conditions had been met. *Id.*

The appeals court expressed no opinion regarding whether the PTO's decision would have been affected if Dr. Vilhardt had disclosed the three declarants' past relationships with Ferring, stating: "While we will never know how the examiners may have weighed the declarations differently, it seems clear to us that this stellar showing of support would have, at the very least, been tarnished." *Id.* 26a. Finally, the appeals court held that the district court's "ultimate finding of inequitable conduct" was not an abuse of discretion. *Id.*[4]

Judge Newman dissented. *Id.* 28a-49a. Disagreeing with both the materiality and intent findings of the majority, Judge Newman charged that the majority had "replac[ed] the need for evidence with a 'should have known' standard of materiality, from which deceptive intent is inferred, even in the total absence of evidence." *Id.* 32a. She noted, "There is no evidence, or even an allegation, that any of these scientists [*i.e.*, Drs. Czernichow, Robinson and Barth] had anything to gain or lose as a result of issuance of the [Ferring] patent." *Id.* 35a.

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[4] The appeals court did not address the district court's alternative holding that Barr did not infringe the Ferring patent.

REASONS FOR GRANTING THE PETITION

This case raises patent law issues of exceptional importance. While allegations of inequitable conduct are easily made, any such ruling overturns the PTO's decision to allow a patent and has enormous practical and financial consequences for the parties involved.[5] WLF agrees with Petitioners that review is warranted on both of the questions presented; we write separately to focus particular attention on the need for this Court to address the types of "material" omissions that warrant judicial refusal to enforce an otherwise valid patent.

Review is warranted because the Federal Circuit has departed so fundamentally from this Court's rationale for creating an "inequitable conduct" defense to a patent infringement claim. As the Court explained more than 60 years ago, "[t]he guiding doctrine" in patent cases in which inequitable conduct is alleged "is the equitable maxim that 'he who comes into equity must come with clean hands.'" *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 814 (1945). The "unclean hands" doctrine "closes the doors of a court of equity to one tainted with inequitableness or bad faith relative to the matter in which he seeks relief." *Id.* An important limitation on application of the unclean hands doctrine is that it has never been applied to a plaintiff based simply on the fact that the plaintiff has engaged in misconduct; rather, the doctrine is strictly limited to situations in which some unconscionable act

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[5] One non-obvious consequence is potentially ruinous litigation: patent holders whose patents are overturned based on findings of inequitable conduct routinely are hit with numerous antitrust class actions alleging that they drove up prices by improperly restraining competition.

committed by the plaintiff has *immediate and necessary* relation to the equity he seeks.

One searches the Federal Circuit's "inequitable conduct" decisions in vain for any indication that that court is basing its decisions on anything remotely resembling the "unclean hands" approach mandated by *Precision Instrument.* Instead, the Federal Circuit has developed an elaborate set of rules for determining when omitted information should be deemed material and when the patentee should be deemed to have acted with the requisite intent. All too frequently, the result of those rules has been travesties such as the decision at issue here: a patent is struck down based on alleged "inequitable conduct" despite *the absence of even an allegation* that any of the information submitted in support of the patent was false or misleading. By interpreting materiality so broadly, the Federal Circuit in essence is attempting to write the rules of evidence for the PTO; such rules have little relationship to the "unclean hands" doctrine and – because they are being written after the fact – have thrown into doubt the validity of numerous existing patents. Review is warranted to resolve the sharp conflict between this Court's understanding of "inequitable conduct" and the Federal Circuit's recent "inequitable conduct" decisions.

Review is also warranted because of the tremendous uncertainty among patent holders being created by the Federal Circuit's inequitable conduct decisions. At the same time that the Federal Circuit is inexorably expanding the definition of a "material" omission, it has declined to provide precise guidelines regarding what evidence must be submitted to the PTO and has made absolutely clear that it does not deem itself bound by any evidentiary rules established by the PTO. The result is that applicants must guess regarding what evidence must be submitted, with the potential penalty for a wrong

guess being the invalidation of an otherwise valid patent. Moreover, given the Federal Circuit's demonstrated willingness to apply its broadened standards to patents issued 15 or more years ago, an applicant's guessing game entails determining not only what the Federal Circuit might deem "material" today but also what it might deem "material" 15 years from now. Review is warranted to permit this Court to establish a readily comprehensible inequitable conduct standard on which applicants can rely.

Finally, there is no merit to Barr's contention that Petitioners have in some manner waived their right to challenge the Federal Circuit's materiality and intent standards. Throughout these proceedings, Petitioners have contested allegations that information omitted from the Ferring Patent application was material and that those alleged omissions were undertaken with an intent to deceive the PTO. By raising those issues below, Petitioners have preserved the right to raise them again in this Court – and to introduce any and all arguments relevant to those issues, including arguments that the Federal Circuit's broad definitions of materiality and intent are inconsistent with this Court's approach to "inequitable conduct" cases.

I. REVIEW IS WARRANTED BECAUSE THE DECISION BELOW CONFLICTS WITH THIS COURT'S UNDERSTANDING OF WHAT CONSTITUTES "INEQUITABLE CONDUCT"

It has now been more than 60 years since the Court last addressed the circumstances under which an otherwise-valid patent should be held unenforceable based on the applicant's inequitable conduct before the Patent Office. That case, *Precision Instrument,* held a patent unenforceable based on findings that: (1) Automotive, the applicant, learned that a

competing applicant had committed perjury during interference proceedings; (2) Automotive used that information to blackmail the competing applicant into assigning his patent rights to Automotive and agreeing never to contest the resulting patent; (3) Automotive never revealed the patent's fraudulent ancestry to the Patent Office; and (4) the result of its actions was that Automotive was issued a patent with claims broader than those to which Automotive was actually entitled. *Precision Instrument*, 324 U.S. at 818-19. The Court held that those facts "all add up to the inescapable conclusion that Automotive has not displayed that standard of conduct requisite to the maintenance of this suit in equity," and it applied the "unclean hands" doctrine to deny enforcement of any part of the patent. *Id.* at 819.

As Petitioners note, in the ensuing decades the federal appeals courts struggled to determine just how close the relationship between omitted information and issues raised in PTO proceedings must be[6] before the omission can be deemed sufficiently material to warrant application of the "unclean hands" doctrine. Pet. 17-18. The appeals courts developed at least three conflicting standards of materiality. *Id.* But following creation of the Federal Circuit, that court chose to adopt none of the three competing definitions of materiality and instead adopted its own, broader definition: information is deemed material where there is "a substantial likelihood" that a reasonable examiner would consider it "important" in deciding to allow the application to issue as a patent. *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362 (Fed. Cir. 1984). In ensuing years, the Federal Circuit has repeatedly expanded its definition of the

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[6] Or between an affirmative misrepresentation and issued raised in PTO proceedings.

information a reasonable examiner would consider important, so that now, as illustrated by the decision below, virtually *any* information that bears on the credibility of any evidence submitted to the PTO on a contested issue is deemed material.

That standard of materiality bears little resemblance to "unclean hands" doctrine and conflicts sharply with this Court's understanding of what constitutes "inequitable conduct." In particular, the Federal Circuit's materiality standard fails to heed this Court's admonition regarding strict limits on application of "unclean hands" doctrine:

> But courts of equity do not make the quality of suitors the test. They apply the maxim requiring clean hands only where some *unconscionable* act of one coming for relief has *immediate and necessary relation* to the equity that he seeks in respect of the matter in litigation.

Keystone Driller Co. v. General Excavator Co., 290 U.S. 240, 245 (1933) (emphasis added).

In *Keystone Driller*, the Court applied "unclean hands" doctrine to dismiss a patent infringement action, where the evidence showed that: (1) an individual may have engaged in prior use of the claimed invention (a circumstance which, if true, would have invalidated a patent); (2) following issuance of the patent, the patentee paid the individual not to disclose his prior use and to sign an affidavit stating that his use of the device was merely an abandoned experiment; and (3) the individual failed to disclose these arrangements in his subsequent deposition. *Id.* at 243. But in other cases, the court has declined to apply "unclean hands" doctrine where the plaintiffs' misconduct did not have a sufficiently "immediate and necessary relation" to the equitable relief sought, to warrant non-enforcement of the patent. *See, e.g., Corona*

Cord Tire Co. v. Donovan Chemical Corp., 276 U.S. 358, 373-74 (1928) (applicant's submission of false affidavits to Patent Office did not warrant non-enforcement of patent, because the falsehoods were not crucial to issuance of the patent).

In more recent times, the Court upheld the NLRB's decision not to apply the "unclean hands" doctrine to bar reinstatement of a fired employee, despite the employee's perjured testimony regarding the reason he was late for work. *Air Freight System, Inc. v. NLRB*, 510 U.S. 317 (1993). The NLRB had reasoned that the perjury was not sufficiently material to the issue of reinstatement, because (the NLRB determined) the employee had actually been fired in retaliation for union activity, not (as the company alleged) because of his tardiness. *Id.* at 321. Similarly, the Fourth Circuit declined to apply the "unclean hands" doctrine to bar an award of equitable relief to a foreign government accused of persecuting a political opponent, where there was no "close nexus between a party's unethical conduct and the transactions on which that party seeks relief." *Republic of Rwanda v. Uwimana*, 274 F.3d 806, 810 (4th Cir. 2001) (citing *Keystone Driller*).

The Federal Circuit's determination in this case – that virtually any evidence that bears on credibility of material evidence should itself be deemed material for purposes of adjudicating "inequitable conduct" claims – cannot be squared with *Precision Instrument* and *Keystone Driller*. Such credibility evidence can rarely, if ever, be deemed to bear an "immediate and necessary relation" (*Keystone Driller*, 290 U.S. at 245) to whether the Ferring Patent should have been issued. Even if the Federal Circuit were correct that a reasonable examiner would have thought it "important" that Drs. Czernichow, Robinson, and Barth had prior professional relationships with Ferring, such evidence is sufficiently

tangential to the accuracy of their declarations that it cannot meet *Keystone Driller*'s "immediate and necessary relation" test. That is particularly true where, as here, there is no evidence in the record seriously calling into question the accuracy of their declarations.[7]

The declarants' prior professional relationships with Ferring is rendered all the more tangential when one considers that their testimony was cumulative. Dr. Miller provided declarations stating that neither the Zaoral Patent nor the Vavra reference, nor the two of them in tandem, suggested oral administration of DDAVP for gastrointestinal absorption. Dr. Miller's lack of a prior relationship with Ferring has never been questioned. Because his testimony covered the same ground covered by the Czernichow, Robinson, and Barth declarations, there is little reason to suppose that an examiner would have reached a different patenting decision even if he or she had totally discounted the other three declarations for bias. Indeed, the PTO explicitly excludes, from its own definition of "material" information, any information that is "cumulative to information already of record or being made of record in the application." 37 C.F.R. § 1.56(b), Pet. App. 96a.

The appeals court nonetheless made clear that it considers a declarant's past relationship with a patent applicant

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[7] That assessment does not change simply because an examiner in 1986 recommended to Dr. Vilhardt that he obtain "non-inventor" statements (a recommendation not repeated when Dr. Vilhardt collected his second round of declarations four years later). Dr. Vilhardt literally complied with that request: none of the declarants other than Dr. Vilhardt was an inventor of the claimed invention. Moreover, the prior relationships that Drs. Czernichow, Robinson, and Barth had with Ferring made them far less interested witnesses than if, for example, they were being paid for their testimony or if they stood to profit from the patenting or marketing of the claimed invention.

to be "material" *whenever* the declarant's views are material to a contested issue in the application process and the relationship is a "significant" one. Pet. App. 13a-14a. Indeed, the appeals court for some unspecified reason determined that the past relationships in this case (particularly Dr. Robinson's) were "highly material," *id.* 18a and 25a, a determination that caused the appeals court to apply a relaxed standard for finding "intent" to deceive. The court made clear that this expansive definition of "material" applies to any evidence of past relationships between a declarant and a patent applicant, regardless of whether the declarant's statements are cumulative. Review is warranted to resolve the conflict between that Federal Circuit standard and this Court's admonition that the "unclean hands" doctrine only applies when *Keystone Driller*'s "immediate and necessary relation" test is met.

II. REVIEW IS WARRANTED BECAUSE OF THE TREMENDOUS UNCERTAINTY BEING CREATED BY THE FEDERAL CIRCUIT'S INEQUITABLE CONDUCT DECISIONS

As Petitioners have well documented, the Federal Circuit's expansion of the inequitable conduct doctrine far beyond its unclean hands origins has led to inclusion of inequitable conduct defenses in virtually all patent infringement actions. Pet. 12-13. The Federal Circuit itself has described the proliferation of such claims as "an absolute plague" on the patent system. *Burlington Industries, Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988). The Federal Circuit attempted to address that problem a number of years ago by tightening somewhat the standards for establishing that a patent applicant intended to deceive the PTO. *See Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876-77 (Fed. Cir. 1988) (*en banc*). But

Kingsdown did not address the Federal Circuit's overly broad materiality standard, and in the intervening years, the circuit's definitions of materiality and intent have only grown more encompassing. As Judge Newman argued in dissent, the majority:

> [N]ot only ignore[s] *Kingsdown* and restore[s] a casually subjective standard, they also impose a positive inference of wrongdoing, replacing the need for evidence with a "should have known" standard of materiality, from which deceptive intent is inferred, even in the total absence of evidence. Thus the panel majority infers material misrepresentation, infers malevolent intent, presumes inequitable conduct, and wipes out a valuable property right, all on summary judgment, on the theory that the inventor "should have known" that something might be deemed material.

Pet. App. 32a.

It is difficult to overestimate the chilling effect that such decisions have on the research and development activities that the patent system is intended to foster. If the business community loses faith in the willingness of courts to uphold patents, they are unlikely to be willing to continue to invest the hundreds of millions of dollars typically required to bring a new drug through research and testing and eventually to obtain marketing approval. Indeed, the costs and uncertainties associated with application of the inequitable conduct doctrine led the National Research Council of the National Academies of Science and Engineering in 2004 to recommend "the elimination of the inequitable conduct doctrine or changes in its implementation." National Research Council, *A Patent System for the 21st Century* (2004) at 123, http://www.nap.

edu/html/patentsystem/0309089107.pdf. Review is warranted to prevent the Federal Circuit's inequitable conduct standards from further eroding confidence in our patent system.

The practical problems created for patent applicants by the decision below are readily apparent. Because the Federal Circuit has made plain that it does not feel bound by the PTO's own evidentiary rules in determining what evidence is "material" for inequitable conduct purposes, patent applicants cannot seek guidance from the PTO's rules – which, since at least 1992, have defined materiality considerably more narrowly than does the Federal Circuit. *See* 37 C.F.R. § 1.56, Pet. App. 95a-97a. The decision below puts applicants on notice that *any* evidence relevant to credibility might later be deemed material for purposes of evaluating inequitable conduct claims, because all such evidence might be deemed likely to "interest" a reasonable examiner. For example, since Rule 609 of the Federal Rules of Evidence states that evidence of a criminal conviction is always admissible to impeach witness credibility, applicants may be faulted in future Federal Circuit inequitable conduct decisions for having failed to disclose every criminal conviction of every individual whose declaration is submitted to the PTO. Similarly, despite Fed.R.Civ.P. 26(b)(4), applicants might be faulted for failing to disclose the opinions of non-testifying experts.

While the court below stated that applicants must disclose every "significant" relationship between a declarant and an applicant, it provided little or no guidance regarding what is meant by "significant." Is a friendship between the declarant and the inventor sufficient? What if the declarant and the inventor once worked for the same company, but not the company to whom the patent application has been assigned? What if the inventor in the past signed a declaration that assisted the declarant in obtaining a separate patent of her

own? One might ordinarily think the answer to those questions is "no"; but in light of the decision below – in which a patent was invalidated on the basis of nondisclosure of past relationships under which the declarants had nothing to gain by issuance of the patent – applicants are left with a tremendous amount of uncertainty. In areas of this type, a bright-line rule of some sort – regardless of the form that rule finally takes – is superior to the confusion sown by the current, ill-defined rule. Review is warranted to permit the Court to develop a bright-line rule that will provide clearer guidance to patent applicants.

WLF is not suggesting that applicants need to be provided greater leeway to hide damaging evidence from patent examiners. Indeed, if the PTO determines that it would like applicants to disclose the types of relationships that existed between the declarants and Ferring in this case, WLF would have no objection to the PTO's adoption of an evidentiary rule to that effect. What WLF finds objectionable is the Federal Circuit arrogating to itself the power to write after-the-fact evidentiary rules for the PTO. Review is warranted to permit this Court to determine whether such after-the-fact draftsmanship has a proper place in "unclean hands" and inequitable conduct doctrine.

III. PETITIONERS HAVE NOT WAIVED THEIR RIGHT TO CHALLENGE THE FEDERAL CIRCUIT'S MATERIALITY AND INTENT STANDARDS

In its brief in opposition to the petition, Barr argued that Petitioners have waived their right to challenge the federal circuit's materiality and intent standards. Opp. Br. 13-16. That argument is without merit.

Throughout these proceedings, Petitioners have contested allegations that information omitted from the Ferring Patent application was material and that those alleged omissions were undertaken with an intent to deceive the PTO. By contesting those issues below, Petitioners have preserved the right to contest them again in this Court – and to introduce any and all arguments relevant to those issues, including arguments that the Federal Circuit's broad definitions of materiality and intent are inconsistent with this Court's approach to "inequitable conduct" cases. As the Court has repeatedly explained:

> Our traditional rule is that "once a federal claim is properly presented, a party can make any argument in support of that claim; parties are not limited to the precise arguments they made below."

Lebron v. National Railroad Passenger Corp., 513 U.S. 374, 379 (1995) (quoting *Yee v. City of Escondido*, 503 U.S. 519, 534 (1992)). *See also Harris Trust and Savings Bank v. Salomon Smith Barney Inc.*, 530 U.S. 238, 245 n.2 (2000).

A holding that Petitioners have waived materiality and intent arguments would be particularly inappropriate, because the panel below was, by and large, applying existing Federal Circuit law to the facts of this case and thus lacked authority – assuming it was so inclined – to overturn that existing law. Accordingly, it would serve no purpose to require those in Petitioners position – under threat of waiver – to raise below a challenge to existing Federal Circuit materiality and intent standards when that challenge would inevitably have been denied. It is sufficient that Petitioners throughout this litigation have contested claims that they failed to present material evidence to the examiners and that they did so with an intent to deceive.

Nor is there any merit to Barr's suggestion that the issues raised by Petitioners should be permitted to continue to percolate in the federal appeals courts before they are considered by this Court. Under existing law, the only appeals court that will ever hear patent law issues of this sort is the Federal Circuit. That court has repeatedly rebuffed efforts to scale back on its inequitable conduct case law to eliminate the "plague" of inequitable conduct claims. Delay will not make the issues raised by Petitioners any more suitable for review than they are today. This case provides a particularly suitable vehicle for addressing those issues: because the case comes to the Court on a grant of summary judgment, there are no disputed issues of fact. Rather, the evidence submitted by Petitioners is accepted as true, and all reasonable inferences are to be drawn in their favor. *See, e.g., Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

CONCLUSION

The Washington Legal Foundation respectfully requests that the Court grant the petition for a writ of certiorari.

Respectfully submitted,

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